IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA ex rel. Ryan Bliss, Relator,

STATE OF ARKANSAS ex rel. Ryan Bliss, Relator,

STATE OF CALIFORNIA ex rel. Ryan Bliss, Relator,

STATE OF COLORADO ex rel. Ryan Bliss, Relator,

STATE OF CONNECTICUT ex rel. Ryan Bliss, Relator,

STATE OF DELAWARE ex rel. Ryan Bliss, Relator,

DISTRICT OF COLUMBIA ex rel. Ryan Bliss, Relator,

STATE OF FLORIDA ex rel. Ryan Bliss, Relator,

STATE OF GEORGIA ex rel. Ryan Bliss, Relator,

STATE OF HAWAII ex rel. Ryan Bliss, Relator,

STATE OF ILLINOIS ex rel. Ryan Bliss, Relator,

STATE OF INDIANA ex rel. Ryan Bliss, Relator,

STATE OF IOWA ex rel. Ryan Bliss, Relator,

STATE OF LOUISIANA ex rel. Ryan Bliss, Relator,

STATE OF MARYLAND ex rel. Ryan

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Civil Action No. _____

SA13CA0667

JURY TRIAL DEMAND

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AND UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730

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Bliss, Relator,	§
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STATE OF MASSACHUSETTS ex rel. Ryan Bliss, Relator,	§
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STATE OF MICHIGAN ex rel. Ryan Bliss, Relator,	§
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STATE OF MONTANA ex rel. Ryan Bliss, Relator,	§
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STATE OF NEVADA ex rel. Ryan Bliss, Relator,	§
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STATE OF VIRGINIA ex rel. Ryan Bliss, Relator,	§
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STATE OF WISCONSIN ex rel. Ryan Bliss, Relator,	§
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vs.	§
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BIOCOMPATIBLES INTERNATIONAL PLC, RITA MEDICAL, INC., ANGIODYNAMICS, INC., BTG, PLC and 100 HOSPITALS, Defendants.	§ § § § § § §

COMPLAINT FOR DAMAGES UNDER THE FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS AND DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. In the instant case, relator Ryan Bliss ("Bliss" or "Relator") alleges that the British medical technology firm Biocompatibles International PLC ("BIOCOMPATIBLES"), its parent corporation BTG, PLC ("BTG"), BIOCOMPATIBLES' U.S. distributors RITA Medical, Inc. ("RITA") and AngioDynamics, Inc. ("ANGIODYNAMICS") (collectively "the Device Defendants") and 100 hospitals listed on Exhibit A (collectively the "Hospital Defendants") violated the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and its state law counterparts, through a fraudulent course of conduct that caused federal and state governments to pay large sums of money for a combination drug-device therapy known as Drug Eluting Bead Transarterial Chemoembolization ("DEBTACE"), an off-label medical procedure that involves the use of a drug-eluting bead called LC Bead to deliver the highly-cytotoxic drugs doxorubicin and irinotecan to liver tumors.

2. Relator Bliss worked for Biocompatibles' Distributor RITA as a sales representative during the initial product launch of LC Bead in the United States in 2006 and he continued to sell the product for RITA and ANGIODYNAMICS until July 2008, when he left ANGIODYNAMICS' employment. After an interval working for another company, he joined

BTG/BIOCOMPATIBLES in September 2011 and has had responsibility for marketing LC Bead from that time to the present.

3. Bliss was told by RITA and BIOCOMPATIBLES when he commenced marketing LC Bead in 2006 that the device had a 510k clearance from the FDA and that an identical product called DC Bead sold in the European Union had a CE mark "approval" from the European regulatory authorities.

4. Relator has learned only recently that BIOCOMPATIBLES had no FDA clearance or approval whatsoever for LC Bead until December 2008 and that the clearance it obtained in 2008 was obtained by misrepresenting the actual and intended use of the product as a drug-eluting bead, a matter about which he has extensive knowledge because of his product training for, and experience in, selling LC Bead.

5. Bliss has also learned only recently that DC Bead, the European equivalent of LC Bead, never had any "approval" from European regulatory authorities, as its CE mark certificate was issued by a private testing firm, and that an identical product pre-loaded with doxorubicin was denied approval by European regulatory authorities. Based upon his training and experience in selling LC Bead, he knows that these matters were misrepresented to healthcare providers by representatives of the Device Defendants.

6. Relator has also recently determined, based upon his personal training for, and actual experience promoting LC Bead and the DEBTACE procedure, that the reimbursement codes that the Device Defendants have promoted and which the Hospital Defendants have actually used for billing to government healthcare programs are false and misleading and do not provide enough information about the procedures to permit government contractors to make informed coverage determinations.

7. Finally, Bliss has also ascertained, based upon BTG/BIOCOMPATIBLES sales data in his possession and his knowledge of the sales techniques utilized by all of the Device Defendants for whom he has worked, that the Device Defendants have made direct sales of LC Bead to hospitals operated by the Departments of Defense and Veterans Affairs based upon false and misleading statements about the regulatory status, safety and efficacy of LC Bead and the DEBTACE procedure.

8. As a result, government programs have reimbursed healthcare providers for thousands of procedures and drug doses each year, over several years, that would not have been reimbursed had the government healthcare programs known that the procedures in question were wholly investigational and experimental and therefore lacking in requisite medically necessity.

9. Revenues from sales to hospitals of LC Bead in the United States by ANGIODYNAMICS were $22.4 million in fiscal year 2010, $28.3 million in fiscal year 2011 and $21.3 million for the portion of fiscal year 2012 that the company held distribution rights for the product. Revenues from sales to hospitals of LC Bead by BTG/BIOCOMPATIBLES from January 1, 2012 through June 21, 2013 have been approximately $41 million. Thus, total hospital sales of LC Bead from 2010 through the present have been approximately $113 million, approximately half of which were for military hospitals or billed to government healthcare programs by private hospitals. With related drug, facility and physician charges estimated to be three times the cost of the devices themselves, the cost to federal and state programs has been approximately $170 million since 2010, not including charges for procedures performed between 2006 and 2010.

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II. PARTIES

10. Relator Ryan Bliss is a citizen of the Unites States and resides in Boston, Massachusetts. Mr. Bliss was employed by defendant RITA from November 2005 until January 2007 when RITA was acquired by ANGIODYNAMICS. He was employed by ANGIODYNAMICS from January 2007 until July 2008. He has been employed by BIOCOMPATIBLES, a subsidiary of BTG, since September 2011 and currently serves as Product Manager for the Interventional Medicine Division in the U.S. and Canada. Mr. Bliss had responsibility for marketing BIOCOMPATIBLES' drug-eluting beads in the United States, either as a sales representative or a manager, from the initial product launch by RITA in July 2006 through July 2008 and again from September 2011 through and including the present.

11. The allegations of this complaint are based upon the direct, personal observations of Mr. Bliss, non-public documents in his possession and/or an investigation conducted by Mr. Bliss and his counsel that adds materially to any transactions that have been publicly disclosed.

12. Mr. Bliss provided to the Department of Justice and the Attorneys General of all of the States named in the caption and the District of Columbia a full disclosure of substantially all material facts, as required by the False Claims Act, 31 U.S.C. § 3730(b)(2), and relevant state statutes, prior to filing the instant complaint. He therefore qualifies as an "original source" within the meaning of the False Claims Act.

13. Defendant Biocompatibles International, plc. ("BIOCOMPATIBLES") is a medical technology company organized in the United Kingdom with its principal place of business at Chapman House, Farnham Business Park, Weydon Lane, Farnham, Surrey GU9 8QL. BIOCOMPATIBLES was publicly-traded on the London Stock Exchange under the symbol "BII" until it was acquired on or about January 11, 2011, by BTG plc, a publicly-traded

company also organized in the United Kingdom. BIOCOMPATIBLES has operated in the United States through various subsidiaries, including Biocompatibles UK Ltd and Biocompatibles, Inc. and a subsidiary of its parent company, BTG International Inc. BIOCOMPATIBLES maintains offices in the United States at Five Tower Bridge, 300 Barr Harbor Drive, Suite 800, West Conshohocken, PA 19428-2998 and 115 Hurley Road, Building 3, Oxford, CT 06478.

14. Defendant RITA Medical Systems, Inc. is a Delaware corporation with its principal place of business at 46421 Landing Parkway, Fremont, CA 94538. It is presently a subsidiary of ANGIODYNAMICS, which acquired it on January 29, 2007, but it was formerly publicly-traded under the symbol RITA. From approximately 2006 until its acquisition by ANGIODYNAMICS, RITA held the exclusive distribution rights to BIOCOMPATIBLES' LC Bead product in the United States by virtue of a Supply and Distribution Agreement with Biocompatibles, UK Ltd, a subsidiary of BIOCOMPATIBLES.

15. Defendant AngioDynamics, Inc., ("ANGIODYNAMICS") is a Delaware corporation with its principal place of business at 14 Plaza Drive, Latham, New York 12110. Its stock is publicly traded under the symbol "ANGO." From January 29, 2007, until December 31, 2011, ANGIODYNAMICS held the exclusive distribution rights to BIOCOMPATIBLES' LC Bead product in the United States by virtue of a Supply and Distribution Agreement with Biocompatibles UK Ltd, a subsidiary of BIOCOMPATIBLES.

16. BTG, plc. ("BTG") is a publicly-traded, medical technology company organized in the United Kingdom with its principal place of business at 5 Fleet Place, London EC4M 7RD, UK. It does business in the United States through its subsidiary BTG International Inc., whose principal place of business is at Five Tower Bridge, 300 Barr Harbor Drive, Suite 800, West

Conshohocken, PA 19428-2998 and/or Biocompatibles, Inc., whose principal place of business is at 115 Hurley Road, Building 3, Oxford, CT 06478.

17. The Defendant Hospitals listed on Exhibit A are the top 100 hospitals in the United States that have purchased LC Bead from the Device Defendants and falsely billed government healthcare programs for non-reimbursable DEBTACE procedures utilizing LC Bead and the drugs doxorubicin and irinotecan.

III. JURISDICTION AND VENUE

18. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This court also has jurisdiction pursuant to 28 U.S.C. § 1345 and 28 U.S.C. § 1331. Supplemental jurisdiction for Counts Three through Thirty-One arises under 28 U.S.C. § 1367, since these claims are so related to the federal claims that they form part of the same case or controversy under Article III of the U.S. Constitution.

19. At all times material to this Complaint the Device Defendants regularly conducted substantial business within every state of the Union, including the state of Texas. A number of the Defendant Hospitals do business in the state of Texas and several of the military and veterans hospitals are located in Texas. Since the False Claims Act provides for nationwide service of process, all Defendants are subject to personal jurisdiction in the state of Texas.

20. Venue is proper in this district, among others, pursuant to 31 U.S.C. § 3732(a) because many of the Defendants transact business in this district and the federal Departments of Defense and Veterans Affairs have hospital facilities in this district that were impacted by the fraudulent course of conduct described herein.

IV. ALLEGATIONS

A. MEDICAL, TECHNICAL & CODING BACKGROUND

21. The principal diseases treated with the drug-eluting beads at issue in this case are (1) primary liver cancer (hepatocellular carcinoma or "HCC"), a cancer that originates in the liver, frequently in association with cirrhosis or hepatitis; and (2) metastatic liver cancer associated with the spread of colorectal cancer ("mCRC"). HCC is sometimes treated off-label with doxorubicin and mCRC is sometimes treated off-label with irinotecan, both of which are chemotherapeutic drugs approved for systemic administration via intravenous injection to treat certain non-localized cancers, but not for treatment of liver cancer and not for targeted delivery to the site of a localized tumor via drug eluting beads.

22. Doxorubicin is a cytotoxic and potentially lethal anthracycline class antibiotic, now available as a non-patented generic, that was manufactured by Pharmacea and Upjohn under the brand name Adriamycin and by Bristol-Myers-Squib under the brand name Rubex. Doxorubicin has an FDA approved indication for systemic delivery through the bloodstream "to produce regression in disseminated neoplastic conditions" (abnormal masses of tissue, whether benign, pre-cancerous or cancerous, that result from abnormal growth or division of cells and have spread beyond their point of origin using the bloodstream to "seed" other areas of the body), as well as "lymph node involvement following resection of primary breast cancer," but does not have an approved indication for targeted delivery to localized "primary" cancers like HCC, which are confined to the tissue of a single organ.

23. Because doxorubicin's natural color is red and because the drug can produce life-threatening and otherwise serious side effects, including cardiac arrest, congestive heart failure,[1] deadly bowel infections, painful eruptions on the palms of the hands and feet, hair loss, nausea and vomiting, it is sometimes referred to as "red devil" or "red death."

24. Irinotecan is another dangerous drug now available in generic form that was formerly manufactured by Pfizer under the brand name Camptosar. It has been approved only for intravenous injection/infusion as a first-line therapy in combination with other drugs for patients with colorectal cancer and administered as a stand-alone treatment for patients with colorectal cancer whose disease has recurred or progressed following an initial combination therapy. It has not been approved as a stand-alone treatment for administration through the route of drug-eluting beads to treat patients with cancer of the liver secondary to colorectal cancer.

25. Dangerous side effects of irinotecan include very serious, clinically significant diarrhea; serious, possibly fatal blood disorders, including bone marrow failure leading to low red and white blood cell counts as well as low platelet counts; and extreme suppression of the immune system, which can lead to fatal infections.

26. The medical devices at issue in this case are drug-eluting beads manufactured and sold by defendant BIOCOMPATIBLES. Beads sold under the trade names DC Bead and LC Bead are designed to be loaded with doxorubicin or irinotecan by the end user. DC Bead, which is sold in Europe, and LC Bead, which is sold in the United States, are identical products.

[1] Rowan Chlebowski et al, Adriamycin (Doxorubicin) Cardiotoxicity: A Review, WES.T J. MED. 131:364-368, Nov. 1979. This article describes the mechanism of damage to the heart. Congestive heart failure experienced by a patient with cancer would not necessarily be attributed to the doxorubicin, meaning the extent of damage from LC Bead loaded with doxorubicin cannot be known with any exactitude.

BIOCOMPATIBLES also has versions of the same beads pre-loaded with doxorubicin and irinotecan that are not yet on the market, but will be sold under the trade names PRECISION Bead and PARAGON Bead (PRECISION for doxorubicin-loaded beads; PARAGON for irinotecan-loaded beads) if they are ever approved by the FDA.

27. All of these beads are tiny, compressible, jelly-like microspheres packaged in saline solution in small vials, with the beads tinted light blue for better visualization until loaded with drug, when they change color to red (if loaded with doxorubicin) or a darker blue (if loaded with irinotecan). Drug loading for the DC Bead and LC Bead is typically performed by a hospital pharmacist, who injects doxorubicin or irinotecan into the vial and waits for the beads to absorb the drug. The beads are so tiny that they can be withdrawn from the vial through a needle attached to a syringe and injected into a catheter for delivery to a blood vessel feeding a tumor.

28. These drug-eluting beads are composed of a water-insoluble, water-swellable polyvinyl alcohol ("PVA") matrix that absorbs water to form a hydrogel. The PVA beads are engineered for drug loading and elution by adding to the polymer matrix high concentrations of an anionic sulfonate monomer referred to as "AMPS." The AMPS molecules have a negative ionic charge.

29. Doxorubicin, irinotecan and other drugs with a positive ionic charge displace water in the PVA beads and bond with the AMPS molecules when mixed with the PVA beads in a vial by the end user (typically a hospital pharmacist) or when pre-loaded onto the beads at BIOCOMPATIBLES' manufacturing facility (in the case of the PRECISION and PARAGON beads that have not yet been placed on the market). When the beads are injected via a catheter into a blood vessel feeding a tumor, the drug gradually elutes from the beads over a period of

approximately 14 days and is carried into the tumor by a continued flow of blood through the vessel into the tumor.

30. Vials of the drug-eluting beads cost approximately $2,000-$3,000 per vial. BIOCOMPATIBLES also makes a much cheaper PVA microsphere product known as Bead Block that comes in a syringe instead of vial, sells for approximately $300 per syringe but does not contain a high-enough concentration of AMPS to be functional as a drug-eluting bead. Bead Block contain 90% PVA and 10% AMPS; whereas DC Bead, LC Bead, PRECISION Bead and PARAGON Bead contain 55% PVA and 45% AMPS.

31. Bead Block is used for "bland" embolization procedures (in which the beads occlude blood flow and do not elute drugs) in a well-established procedure known as transarterial embolization ("TAE"). Bead Block is used primarily to treat non-cancerous fibroid tumors of the uterus, but can also be used as a purely embolic device in a procedure known as conventional transarterial chemoembolization ("cTACE") that was developed about 30 years ago, where embolic beads are utilized to seal off chemotherapeutic drugs injected into the blood vessels feeding a tumor. The DC, LC, PRECISION and PARAGON beads are used in a new and experimental procedure first developed around 2002 that is known as drug-eluting bead transarterial chemoembolization ("DEBTACE"), where chemotherapeutic drugs are delivered to liver tumors by means of drug-eluting beads rather than by injection.

32. BIOCOMPATIBLES' DC, LC, PRECISION and PARAGON beads are all the same drug-eluting bead product, with the only distinctions being that the DC Bead is labeled for sale in Europe, the LC Bead is labeled for sale in the United States, the PRECISION bead is pre-loaded with doxorubicin and the PARAGON bead is pre-loaded with irinotecan. DC Bead and LC Beads often come from the same manufacturing batches.

33. The principal medical procedure at issue in this case is DEBTACE, which is distinguishable from both TAE and cTACE not only by the beads used to perform the procedure (i.e. LC Bead or another drug-eluting bead in DEBTACE vs. Bead Block or another manufacturer's embolic bead in TAE or cTACE), but also by the "endpoint" sought from use of the beads (embolization or occlusion of the tumor is the desired endpoint in TAE and cTACE procedures vs. the endpoint of continued blood flow, also called sluggish flow or near stasis, and complete drug delivery, in DEBTACE procedures). These endpoint distinctions also drive the selection of proper CPT codes for billing government healthcare programs and whether the procedures are reimbursable under government healthcare programs as discussed below.

34. In all three procedures, an interventional radiologist uses a catheter inserted into an artery that is threaded through the vasculature until it is positioned in the principle blood vessel feeding a tumor. In the traditional TAE procedure, which does not include injection of a chemotherapeutic drug, an embolic bead product like Bead Block is injected through the catheter to the site of the tumor (in current practice, mostly fibroid tumors of the uterus), where the beads block the flow of blood into the tumor, starving it of nutrients and thereby causing its tissue to shrink or die.

35. TAE is a well-known, medically-accepted procedure that has been in use for decades, has a CPT code assigned to it by the American Medical Association and is reimbursable under government healthcare programs. The CPT code assigned to TAE, CPT 37204, is described as "[t]ranscatheter ***occlusion or embolization*** (eg, tumor destruction, achieve hemostasis, occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head/neck." (emphasis added). Embolization is defined as "[a] treatment that clogs

small blood vessels and blocks the flow of blood, such as to a tumor."[2] To occlude is to "[t]o close, obstruct, or prevent the passage" and "[t]o occlude an artery is to occlude the flow of blood."[3]

36. Because TAE is a medically-accepted form of therapeutic embolization that uses embolic beads for their FDA cleared indication, it has been approved for reimbursement by Medicare and Medicaid in a National Coverage Determination ("NCD") issued by the Centers for Medicare and Medicaid Services ("CMS"). *See* NCD 100-3, Medicare Manual Section 20.28 (effective 12/15/1978). It is properly billed using CPT Code 37204.

37. The cTACE procedure is also well-established, having been in use for approximately 30 years, but involves a chemotherapeutic agent like doxorubicin mixed in an iodized oil emulsion called lipiodol which is injected into a blood vessel at the site of a tumor, followed by a bland embolic device like Bead Block that is used to prevent backflow of the cytotoxic drug into the blood stream and also to occlude or block the flow of blood through the vessel feeding the tumor.

38. Although CPT code 37204 was not developed for cTACE, the code arguably describes the cTACE procedure because the endpoint of the embolic bead use in cTACE is "occlusion or embolization." Government healthcare programs typically reimburse for cTACE, which is typically billed using CPT code 37204, although there have been no national or local coverage determinations specifically addressing the coverage issue and the question of the propriety of the use of this code for cTACE and coverage for the procedure must be considered to be an open question.

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[2] *See* Medicine.Net's MEDTERMS DICTIONARY, http://www.medterms.com/script/main/art.asp?articlekey=3223 (last visited July 15, 2013).

[3] *Id.* at http://www.medterms.com/script/main/art.asp?articlekey=20657 (last viewed July 15, 2013).

39. The DEBTACE procedure promoted by BIOCOMPATIBLES is a new and investigational procedure that uses drug-eluting beads to deliver chemotherapy to the tumor in lieu of an injection of the chemotherapeutic drug mixed with lipiodol. In the DEBTACE procedure, the endpoint of the beads is to deliver the drug to the tumor, not to cut off blood flow through occlusion or embolization, as described by CPT 37204. In fact the endpoint of DEBTACE is a continued but reduced flow of blood to the tumor in order that the drug eluted by the beads may be carried into the tumor over a period of 14 days and the beads themselves will be carried toward the tumor rather than being refluxed into the circulatory system, with potentially dire consequences.[4] The desired endpoint of reducing blood flow and complete delivery of the drug for the DEBTACE procedure means that the vessel feeding the tumor remains patent, or open, which allows the physician to have vascular access to that tumor should he/she need to re-treat the tumor with DEBTACE again in the case that the first DEBTACE procedure was not successful at treating the tumor completely.

40. BIOCOMPATIBLES claims that the slow release of doxorubicin or irinotecan from the beads is less likely than cTACE or systemic chemotherapy to result in circulation of

[4] *See* Liapi, Eleni & Geschwind, Jean-Francois H., "Transcatheter Arterial Chemoembolization for Liver Cancer: Is It Time to Distinguish Conventional from Drug-Eluting Chemoembolization?," CARDIOVASC INTERVENT RADIOL DOI 10.1007/s00270-010-0012-y (November 12, 2010) (stating on p. 6 that although both occlusive and non-occlusive techniques have been described for both cTACE and DEBTACE, "It is critically important when DEBs [drug eluting beads] are used to ensure that forward flow exists at all times to avoid reflux along the catheter, which could result in nontarget embolization and possible dire consequences (gastroduodenal ulceration, pancreatitis, cholecystitis)." *See also* Lencioni , Riccardo, 2011 GLOBAL EMBOLIZATION SYMPOSIUM AND TECHNOLOGIES CONFERENCE, Paris, France April 27-30, 2011, "Review of Treatment Algorithms and Procedural Standards for DC Bead in HCC" (stating at p. 4 that "Injection should be continued until near stasis is observed in the artery directly feeding the tumor (i.e., the contrast column should clear within 2–5 heartbeats). At that point, injection must be stopped, regardless of the amount of beads that have been actually administered, to avoid reflux of embolic material.") and Rilling, William, SYMPOSIUM ON CLINICAL INTERVENTIONAL ONCOLOGY held Jan 14-15, 2012 in Miami FL , "Tips & Tricks for DEBTACE," (stating on slide 12 that the endpoint for DEB-DOX (DEBTACE) is "near stasis" and the goal is drug delivery). Near stasis means blood flow is reduced, but not occluded. Therefore, the endpoint of DEBTACE is drug delivery through continued but reduced blood flow; not a total occlusion of blood flow.

high levels of cytotoxic drug to other organs of the body. However, DEBTACE involves risks not present with cTACE or systemic chemotherapy because the drug-loaded beads can be shunted to vital organs such as the lungs where they lodge, causing pulmonary embolism with beads that are loaded with a cytotoxic chemotherapeutic agent and resulting death,[5] and there is a much higher incidence of life-threatening damage to the liver and biliary tract with DEBTACE.[6]

41. The DEBTACE procedure involves an off-label use of doxorubicin or irinotecan because the approved route of administration of the drugs is intravenous injection (as arguably occurs with cTACE), not elution at the site of a tumor from a drug-eluting bead, and also because the drugs are not even approved for treatment of liver tumors. Furthermore, the LC Bead as marketed in the United States since April 17, 2006, for the DEBTACE procedure had no FDA clearance whatsoever until December 24, 2008, and was cleared then only for traditional embolic uses to block blood flow to tumors, not as a drug-delivery device requiring continued sluggish blood flow to a tumor so that the drugs can be swept into the tumor over a period of 14 days as they elute from the beads.

42. The only randomized, single-blind, controlled trial of DEBTACE versus TAE for HCC (liver cancer) found no improvement in response rate, median time to progression, progression-free survival or overall survival rates despite the higher cost of the DEBTACE procedure utilizing doxorubicin-eluting beads. *See* Brown, et al, "A Randomized, Single-Blind, Controlled Trial of Beads Versus Doxorubicin-Eluting Beads for Arterial Embolization of

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[5] *See* Khan et al, "Acute Lung Injury Following Transcatheter Hepatic Arterial Chemoembolization of Doxorubicin-Loaded LC Beads in a Patient with Hepatocellular Carcinoma," LUNG INDIA, 2012 Apr; 29(2): 169-72.
[6] *See* Guiu et al, "Liver/Biliary Injuries Following Chemoembolization of Endocrine Tumours and Hepatocellular Carcinoma: Lipiodol vs. Drug-Eluting Beads," JOURNAL OF HEPATOLOGY 2012 vol. 56 j 609–617.

Hepatocellular Carcinoma (HCC)," *GiCS* 2013; Abstract 143. The EU regulatory authorities denied approval for BIOCOMPATIBLES' PRECISION beads pre-loaded with doxorubicin in early 2008, concluding that the safety risks presented by the devices were not outweighed by their limited efficacy

43. DEBTACE has no national or local coverage determinations approving it for reimbursement by Medicare, Medicaid, TRICARE or CHAMPVA. Moreover, government healthcare programs do not know that a coverage determination is required for DEBTACE because the procedure is falsely billed as traditional TAE or cTACE by using CPT code 37204, which does not accurately describe the new, experimental and off-label procedure.

B. FDA APPROVAL OF DRUGS, DEVICES & COMBINATION PRODUCTS

Drugs

44. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a) & (d).

45. The FDA does not approve a drug in general. Instead, a drug is approved for administration in a certain manner (pill taken orally, intravenous injection etc.), in specified dosages, and for treatment of a specific condition known as its indication. FDA approval is based on data generated in randomized and well-controlled clinical trials, typically lasting a number of years, which must demonstrate to the satisfaction of the FDA that the drug will be safe and effective for its intended use.

46. The indication, dosages and route of administration approved by the FDA are set forth in the drug's label, or the printed insert in the drug's packaging. The FDA will only

approve the new drug application if the label conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label," which refers to the use of an approved drug for any purpose, or in any manner, other than what is described on the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, treating the condition through a different route of administration, or treating a different patient population (i.e., treating a child when the drug is approved to treat adults only).

47. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different from those approved by the FDA. However, the law prohibits marketing or promoting a drug for any use that the FDA has not approved. 21 U.S.C. §§ 331, 352.

48. Doxorubicin (as approved by the FDA for Pharmacea and Upjohn's brands Adriamycin RDF and Adriamycin PFS and generic equivalents) has been approved for intravenous injection/infusion to produce regression in disseminated neoplastic conditions [non-localized metastatic cancers], including a long list of specific cancers that does not include liver cancer. It is also indicated for use as a component of adjuvant therapy in women with evidence of axillary lymph node involvement following resection of primary breast cancer. It has not been approved for administration through the route of drug-eluting beads to treat primary liver cancer (HCC), which is a localized cancer originating in the liver.

49. Doxorubicin (as approved by the FDA for Jannsen's brand Doxil and generic equivalents) has been approved for intravenous injection/infusion for ovarian cancer after failure of platinum-based chemotherapy, AIDS-related Kaposi's Sarcoma after failure of prior systemic

chemotherapy or intolerance to such therapy and multiple myeloma in combination with bortezomib in patients who have not previously received bortezomib and have received at least one prior therapy. It has not been approved for administration through the route of drug-eluting beads to treat primary liver cancer (HCC).

50. Doxorubicin (as approved by the FDA for Bristol-Myers-Squibb's brand Rubex and generic equivalents) has been approved for intravenous injection/infusion to produce regression in disseminated neoplastic conditions [non-localized metastatic cancers], including a long list of specific cancers that does not include liver cancer. It has not been approved for administration through the route of drug-eluting beads to treat primary liver cancer (HCC).

51. The medical device manufacturer Delcath Systems has obtained an initial orphan drug "designation" for doxorubicin to treat HCC and is conducting clinical trials involving the targeted administration of high dosages of doxorubicin to liver tumors using its catheter devices, but the drug has not been approved by the FDA as safe and effective for this indication and FDA approval does not appear to be likely.[7] In fact, A Food and Drug Administration advisory panel has recommended that the FDA reject Delcath Systems Inc.'s chemotherapy system because 8 of the 122 patients treated in clinical trials died as a result of complications from the treatment.

52. Irinotecan (Pfizer's brand Camptosar and generic equivalents) has been approved only for intravenous injection/infusion as a first-line therapy in combination with 5-fluorouracil

[7] The FDA "designation" simply means that the patient population with HCC is small enough that orphan drug rules will control this drug application and Delcath Systems will be granted the exclusive right to sell the drug for this indication if it obtains an FDA approval for treatment of HCC through this route of administration. An FDA advisory panel of 16 oncologists recommended that the FDA reject approval of Delcath's doxorubicin chemotherapy system. The vote was 16-0 in support of rejecting approval for the Delcath system. *See* http://www.bizjournals.com/albany/morning_call/2013/05/fda-advised-to-reject-delcaths-chemo.html (last visited June 3, 2013). A securities fraud class action has been filed in the U.S. District Court for the Southern District of New York against Delcath. This is because Delcath allegedly withheld the fact that 7% of the 122 patients treated with the Delcath system died as a direct result of treatment. *See* http://www.securitieslawfirm.com/securities-fraud-class-actions/delcath-systems-dcth-securities-fraud-class-action-lawsuit (last visited June 3, 2013).

and leucovorin for patients with metastatic carcinoma of the colon (mCRC) or rectum and administered as a stand-alone treatment for patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following initial fluorouracil-based therapy. It has not been approved as a stand-alone treatment for administration through the route of drug-eluting beads to treat patients with cancer of the liver secondary to mCRC.

53. The Device Defendants have violated the FDA's drug marking rules by promoting doxorubicin and irinotecan to treat HCC and liver metastases from colorectal cancer, indications for which they are not approved, and by an unapproved route of administration, i.e. the DEBTACE procedure involving targeted delivery of the drugs to the liver via drug-eluting beads. Neither drug is approved for treatment of liver cancer and neither drug is approved for any route of administration other than intravenous injection/infusion.

Medical Devices

54. Likewise, no medical device may be marketed in the United States without prior approval by the FDA for its intended use. 21 U.S.C. § 360.

55. The Food, Drug and Cosmetics Act ("FDCA") was amended in 1976 to give the FDA a gatekeeper role in approving the safety and effectiveness of medical devices similar to its role in regulating prescription drugs. Section 513 of the FDCA (21 U.S.C. § 360c) requires the FDA Secretary to classify all medical devices into one of three classes designated as Class I (General Controls), Class II (Special Controls) and Class III (Premarket Approval) depending upon the level of regulation required to assure their safety and effectiveness.

56. Class III devices, which include items such as replacement heart valves and pacemakers, require a pre-market application ("PMA") demonstrating the safety and effectiveness of the device. Any post-1976 device (that was not introduced into interstate

commerce for commercial distribution before enactment of the 1976 amendments) is classified under Class III by default and requires a PMA demonstrating safety and effectiveness unless it is "substantially equivalent" to a pre-1976 device or the FDA has acted to classify it as a Class I or Class II device. 21 U.S.C. 360c (f) (1).

57. The drug-eluting bead devices at issue in this case, specifically the LC Bead, are Class III devices because they have never been classified by the FDA as Class I or Class II devices and because they are not substantially similar to any pre-1976 device or any device classified in Classes I or II.

58. The only device types classified by the FDA as Class II devices that are even remotely similar to BIOCOMPATIBLES' drug-eluting beads are vascular and neurovascular embolization devices. In seeking pre-market clearance for its drug-eluting beads, it is these devices to which BIOCOMPATIBLES has sought to establish substantial similarity, so the regulations defining those devices are important to the issues presented by this case.

59. The FDA's regulation at 21 CFR § 870.3300 (Vascular embolization device) states that "[a] vascular embolization device is an intravascular implant intended ***to control hemorrhaging*** due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, uterine fibroids), and arteriovenous malformations." (emphasis added). The regulation classifies vascular embolization devices as Class II devices and states that the special controls for such devices are to be found in the FDA guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.

60. 21 CFR § 882.5950 (Neurovascular embolization device) states that "[a] neurovascular embolization device is an intravascular implant intended to permanently ***occlude blood flow*** to cerebral aneurysms and cerebral ateriovenous malformations." (emphasis added).

This regulation also establishes these devices as Class II devices and makes reference to the Special Controls Document.

61. The Special Controls Guidance Document assigns the product code KRD to vascular embolization devices and the code HCG to neurovascular embolization devices. It states that manufacturers seeking 510k clearances for devices of both types are instructed to include a citation to the classification regulation and the product code in their 510k summaries.

62. When BIOCOMPATIBLES sought clearance for its GelSpheres/Bead Block product in 2003 and 2004, it sought approval for those products under the HCG product code and Regulation 882.5950, even though GelSpheres and Bead Block, (which are the same product) are used primarily to embolize uterine fibroid tumors and have very rarely been used in neurovascular procedures.

63. In 2008, BIOCOMPATIBLES submitted its pre-market notification for Bead Block/LC Bead (as though Bead Block and LC Bead were one and the same, when in fact they are entirely distinct) and gave as the reason for its filing that: "[t]his pre-market notification addresses Biocompatibles UK Ltd. intent to market LC Bead with the Vascular (KRD) Code and to update its registration and listing with this code."

64. In summary, BIOCOMPATIBLES obtained clearance for its bland embolic product, Bead Block (aka GelSpheres), as substantially similar to neurovascular embolization devices under FDA product code HCG. It obtained clearance for its drug-eluting bead product, LC Bead, as substantially similar to vascular embolization devices under product code KRD. The LC Bead application was fraudulent because LC Bead is not an embolic device used to occlude blood flow and because BIOCOMPATIBLES did not truthfully disclose the intended use of the device as a drug-delivery system.

65. As stated previously, any post-1976 device (that was not introduced into interstate commerce for commercial distribution before enactment of the 1976 amendments) is classified under Class III by default and requires a PMA demonstrating safety and effectiveness unless it is "substantially equivalent" to a pre-1976 device or the FDA has acted to classify it as a Class I or Class II device. 21 U.S.C. 360c (f) (1).

66. Section 513 of the FDCA, 21 U.S.C. 360c (i), defines "substantial equivalence," with respect to a device being compared to a predicate device, as meaning "that the device has **the same intended use** as the predicate device . . . ." Regulations adopting the same definition appear at 21 CFR 807.100 (b).

67. Intended use is defined in the FDA regulations as "the objective intent of the persons legally responsible for the labeling of devices." 21 CFR 801.4. This regulation further states that:

> The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.

68. Drug-eluting beads like LC Bead that are specifically designed to be utilized in the DEBTACE procedure by loading and eluting doxorubicin or irinotecan are properly classified as Class III devices and are in no way "substantially similar" to vascular and neurovascular embolization devices. They have an entirely different "intended use," drug elution and delivery through continued blood flow over a period of 14 days, which raises different questions of safety and effectiveness from traditional vascular and neurovascular embolization devices designed with the sole purpose to occlude blood flow.

69. If the FDA has made a finding of substantial similarity between the LC Bead and traditional embolization devices, it has done so only because the intended use of the LC Bead was misrepresented by BIOCOMPATIBLES. The company's failure to disclose in its 2008 pre-market notification for LC Bead that the product was intended for use as a chemotherapeutic drug-eluting bead constituted fraud upon the FDA. Moreover, BIOCOMPATIBLES commenced marketing of LC Bead at least two and a half years before it filed its fraudulent pre-market notification and therefore had no clearance whatsoever when it commenced marketing the product in 2006.

Combination Drug/Device Products

70. When a medical device like BIOCOMPATIBLES' drug-eluting bead is intended to be used in combination with a drug like doxorubicin or irinotecan, the regulatory schemes for both drugs and medical devices are implicated and the product is considered a "combination product." 21 CFR 3.2(e).

71. Combination products are defined by FDA regulation to include not only combinations of drugs and devices that are packaged together (such as the PRECISON bead, which would be packaged with pre-loaded doxorubicin or the PARAGON bead, which would be packaged with pre-loaded irinotecan), but also devices that are packaged separately, but "intended for use only with an approved individually specified drug . . . where both are required to achieve the intended use, indication, or effect intended," (as is the case with LC Bead, which is intended to be used with doxorubicin or irinotecan to achieve its intended effect in the treatment of liver cancer). 21 CFR 3.2(e)(3).

72. A manufacturer seeking to have a combination product approved by the FDA first files a "request for designation," requesting that the Office of Combination Products make a

determination whether the primary mode of action of the combination product is that of a drug or a medical device. Upon determining whether the drug or the device "provides the most important therapeutic action of the combination product," 21 CFR §3.2, the Office of Combination Products assigns the product for pre-market review either on a drug track by the Center for Drug Evaluation and Research or on a device track by the Center for Devices and Radiological Health.

73. BIOCOMPATIBLES has long considered itself a developer of drug-device combination products, of which the drug-eluting bead has been its flagship product. In 2004, the company approached the FDA and obtained a determination that its drug-eluting bead is a combination product that would be evaluated on a device track by the Center for Devices and Radiological Health. In 2005, the FDA granted a conditional IDE for clinical trials to be known as the PRECISION IV trials to assess the safety and efficacy of BIOCOMPATIBLES' drug eluting beads.

74. Nevertheless, BIOCOMPATIBLES never commenced the PRECISION IV clinical trials in the United States but instead elected to place its LC Bead, a drug-eluting combination product, on the market in early 2006 with no pre-market clearance or approval whatsoever. After marketing the product for two and a half years with no clearance, BIOCOMPATIBLES in late 2008 filed a fraudulent 510k notice and obtained marketing clearance for the product as a bland embolization device no different from GelSpheres/Bead Block.

C. UNAUTHORIZED, OFF-LABEL & FALSE MARKETING OF LC BEAD BIOCOMPATIBLES 2003-2005 (BEFORE THE LAUNCH OF LC BEAD)

75. On February 14, 2003, BIOCOMPATIBLES applied for a patent on a drug-eluting bead using a PVA bead technology licensed from BioCure. BIOCOMPATIBLES used its prior expertise with drug-eluting stents to adapt BioCure's PVA bead technology for drug loading and elution by adding negatively-charged sulfonate monomers called "AMPS," which are capable of ionic bonding with drugs like doxorubicin and irinotecan.

76. The patent application explains experiments that BIOCOMPATIBLES conducted to compare the drug-loading capabilities of low-AMPS beads (like GelSpheres/Bead Block) with high-AMPS beads (like DC Bead and LC Bead). By increasing the amount of AMPS in the beads, BIOCOMPATIBLES increased their ability to absorb doxorubicin and similar drugs into the PVA matrix of the beads.

77. The Relator later learned during his RITA product training in 2006 that the GelSpheres/Bead Block product is comprised of 90% PVA and 10%AMPS; whereas the DC/LC Bead product is comprised of 55% PVA and 45% AMPS. With its low concentration of AMPS, GelSpheres/Bead Block is not suitable for loading and eluting drugs, sells for approximately $300 per syringe and prior to 2012 was distributed exclusively by the Japanese firm Terumo for bland embolization procedures, primarily those involving uterine fibroids.

78. BIOCOMPATIBLES named Terumo the exclusive European distributor of Bead Block in March, 2003. Terumo was later named the global distributor of the product on October 23, 2003, a fact of considerable importance to the question whether Bead Block and LC Bead are the same product, as BIOCOMPATIBLES later named RITA and ANGIODYNAMICS as the U.S. distributors of LC Bead. Terumo does not sell therapeutic products for cancer, whereas

RITA was a cancer specialty medical device company before its acquisition by ANGIODYNAMICS. If Bead Block and LC Bead are one and the same product and both are intended for treatment of cancer, BIOCOMPATIBLES would not have granted Terumo an exclusive world-wide distributorship for Bead Block. RITA was chosen to sell LC Bead because LC Bead is a product specifically designed to load and elute cancer drugs.

BIOCOMPATIBLES and RITA (2005-2006)

79. Mr. Bliss was hired by RITA in November, 2005, and was involved in the initial product launch for LC Bead in mid-2006. On May 22, 2006, BIOCOMPATIBLES and RITA entered into a Supply and Distribution Agreement for the LC Bead. It was represented to Relator at the time that BIOCOMPATIBLES had a 510k clearance for the LC Bead, but the document presented to the RITA sales force as proof of this assertion was the FDA clearance letter #K042231 for GelSpheres/Bead Block dated November 12, 2004

80. This would seem to suggest that BIOCOMPATIBLES and RITA considered Bead Block and LC Bead to be one and the same product. However, this is contradicted by the distribution agreement, which contained a clause that precluded BIOCOMPATIBLES from selling competing products or granting third parties the right to sell competing products. It stated: "For the avoidance of doubt RITA acknowledges and agrees that the Biocompatibles 'Bead Block' product shall not be considered a competing product for the purposes of this clause provided the Bead Block product continues to be made of the same material and formulation as the Current Bead Block product."

81. The Bead Block product distributed in the United States by Terumo was not considered a competing product with LC Bead because it was formulated with 90% PVA and 10% AMPS and was not designed for drug loading and delivery; whereas LC Bead was

formulated with 55% PVA and 45% AMPS so it could be used for drug loading and elution. Bead Block and LC Bead were separate, non-competing products in the marketplace and should properly be considered separate and distinct products for regulatory and billing purposes.

82. At the time when RITA obtained the distribution rights for LC Bead, according to an LC Bead Product Training presentation in the Relator's possession, RITA was the only publicly traded medical device company "focused solely on broad based cancer therapies." The LC Bead growth market opportunity was estimated by this presentation to be $50 Million. A RITA presentation in the Relator's possession dated on or about August 2006 entitled "LC Bead New Hire Training," which was given to new sales reps at RITA to train them on the LC Bead product and how to sell it, states on slides #40, #42 and #44 that LC Bead is "***A drug-delivery device….. Specifically designed for chemoembolization…. Has drug uptake ability with doxorubicin (a highly toxic chemotheraputic agent)…. LC Bead can be loaded with any anthracycline family drug. We recommend doxorubicin or adriamyacin… We recommend that pharmacy loads the drug."***

83. Relator was present for all the initial meetings and training sessions for the LC Bead. It was explained to him in these meetings and training sessions by representatives of BIOCOMPATIBLES and RITA that LC Bead would be marketed and promoted solely as a device designed specifically for use in conjunction with chemotherapy drugs as a drug-delivery device and *not* as an embolic device designed to occlude blood flow as stated by BIOCOMPATIBLES in its fraudulent 510(k) filings and by the Defendant Hospitals in their billings using CPT Code 37204.

84. Relator has in his possession a RITA marketing presentation created on or about July 8, 2006, to give to prospective customers and/or analysts about RITA Medical Systems and

their oncology products, which states on slide #35 that LC Bead is "FDA cleared to treat arteriovenous malformations and hypervascular tumors." This marketing statement was knowingly false because RITA knew or should have known that LC Bead had no FDA clearance or approval whatsoever at this time. The BIOCOMPATIBLES product cleared by the FDA was Bead Block, a totally different product distributed by Terumo. LC Bead would not be cleared for another two and a half years, and then only because BIOCOMPATIBLES made fraudulent misrepresentations to the FDA about the product's intended use.

85. From the inception of the LC Bead product launch, the product was promoted and sold solely as a drug-eluting bead for loading with doxorubicin to treat HCC or with irinotecan to treat liver metastases from colorectal cancer. For example, A RITA presentation in the Relator's possession dated on or about July 10, 2006, which was presented to customers and/or analysts about RITA and its oncology products, states on slide #36, that ***"LC Bead is designed to increase the amount of chemotherapy drug delivered to the tumor, designed to increase the length of time the tumor is exposed to the chemotherapy drug, designed to reduce the systemic exposure to the chemotherapy drug and associated toxic side effects."*** Although these statements are true, BIOCOMPATIBLES and RITA knew or should have known that LC Bead was not approved for marketing for any use whatsoever, much less as a drug-eluting bead for use in chemotherapy.

86. On or about July 11, 2006, RITA issued a press release concerning the LC Bead launch in the United States. The product announcement stated "RITA Medical Systems, Inc. (RITA), a publicly-traded medical device company focused solely on cancer therapies, today announced the Company has begun sales of the LC Bead in the United States....The use of the LC Bead for the embolization of hepatocellular carcinoma is reimbursed by Medicare and

Medicaid. Reimbursement includes approximately $1500 per procedure for physicians and a Medicare national average of $6400 facility fees for each in-patient embolization procedure...."

87. This was a fraudulent marketing statement designed to cause the submission of false claims to Medicare and Medicaid because the LC Bead has never been cleared for the treatment of HCC, the DEBTACE procedure that RITA was promoting is an experimental procedure and neither Medicare nor Medicaid had issued a national or local coverage determination suggesting that they would provide reimbursement for the use of a wholly-unapproved product in an experimental procedure for the treatment of HCC.

88. The press release also states ***"The LC Bead is cleared for the embolization of hypervascular tumors and arteriovenous malformations in the United States by the U.S. Food and Drug Administration (FDA)."*** This marketing statement was fraudulent because RITA knew or should have known that LC Bead had no FDA clearance or approval whatsoever at this time. The BIOCOMPATIBLES product cleared by the FDA was Bead Block, a totally different product distributed by Terumo.

89. RITA's product launch meeting for LC Bead was held at the Hotel Valley Ho in Scottsdale, Arizona, in July 2006. The Relator attended this meeting and recalls meeting some of the BIOCOMPATIBLES senior management team there, including Tim Maloney, Vice President of Sales. The purpose of the meeting was to conduct in-depth LC Bead product training so that the sales team would be fully prepared to return to their respective sales territories with the knowledge required to effectively sell LC Bead.

90. Training at this meeting included a PowerPoint presentation from Barbara Burnham, LC Bead Marketing Director. This presentation instructed the sales force about:

a. which drugs are able to load onto LC Bead,

b. how the drug is able to load onto and elute from LC Bead,

c. step-by-step instructions of how to load drug onto LC Bead in the pharmacy,

d. the features and benefits of LC Bead loaded with doxorubicin for treating HCC liver tumors,

e. proper patient selection for chemoembolization,

f. the amount of profit that the hospital will earn by using LC Bead for chemoembolization,

g. how to handle objections about LC Bead from customers,

h. size of the US chemoembolization market,

i. reimbursement codes and fees for chemoembolization,

j. how to sell LC Bead against competitive products,

k. how to sell LC Bead against conventional Transarterial Chemoembolization (cTACE),

l. how to sell LC Bead to Medical Oncologists, Interventional Radiologists. Pharmacists and Nurses,

m. how to understand the studies about drug eluting beads so the sales force could present them to customers effectively, and,

n. how to conduct role plays to practice selling LC Bead for chemoembolization.

91. The Relator and the rest of the entire RITA training team received a copy of the presentation. They also received a Product launch Book comprised of:

a. Market Information about Liver Cancer, HCC, Metastatic Disease, Treatment Options,

b. Chemoembolization Specifics, Overview, Reimbursement, Procedure,

c. Competitive Environment, Market Share, Competitive Overview, Competitive Product Brochures,

d. LC Bead Product Specifics, Product Information, Monograph, Presentation,

e. Financial Summary,

f. Market Field Research Report.

92. As can be seen from the Burnham presentation, RITA was already touting the LC Bead product as a chemotherapy delivery agent. "The drug eluting bead used in the high-dose, current phase of PRECISION is designed to deliver 150 mgs of doxorubicin during each treatment." The marketing presentation was attended by BIOCOMPATIBLES and its information is imputable to that defendant.

93. In the marketing presentation there is a detailed description of Medicare reimbursement for chemoembolization, which states in part that for 2006, the DRG code had an average hospital payment rate of $6,400.61.

94. The training session included a session entitled: **"OK So what is it???(In a nutshell). *A drug-delivery device (Drug-eluting bead or DEB)...specifically designed for Chemoembolization...Has drug uptake ability with doxorubicin (a highly toxic chemotherapeutic agent)...Uptake and release through ion exchange...LC Bead is negatively charged...Dox is positively charged..."**

95. The BIOCOMPATIBLES/RITA strategy to penetrate the U.S. chemoembolization market is most clearly stated in a document entitled "LC Bead sales execution targeting strategies." That document states: "Positioning: Aggressively penetrate chemoembolization market with the LC Bead by leveraging our existing relationships and broad product offering emphasizing RITA's continuum of care, commitment to customer service and

the premium product attributes of the LC Bead embolic. It is all about smart execution.... Initially go after high-volume facilities that currently use the Habib device, RITA RFA and TACE and introduce the continuum of care for quick conversion of the LC Bead...target teaching facilities and educate department heads on the clinical value of RITA's continuum of care. Push the value of a bundles program with one company representative....Finally target high volume BSX RFA and Contour SE users for TACE, introduce Habib and try to convert the RFA ad Bead business."

96. The sales reps were taught to be prepared to answer physician questions about how to know which drug is most effective with the beads. "Reason: Doxorubicin and/or Andriamyacin are very cytotoxic; therefore the other drugs minimize the cytotoxic systemic effects of the therapy." This training is exactly what was used by the sales reps including the Relator, when they went out to speak to physicians. The off-label promotion was open, unbridled and not in the least inhibited by the limited FDA 510k clearance for GelSpheres/Bead Block and lack of any clearance for LC Bead.

97. The training also offered citations for studies and recommended answers to various questions that might be asked by the doctors all about the delivery of chemotherapy. On the last page the reps are asked **"So...Are you ready to hit the field with this incredible product? Launch is NOW...You have continuous support between the RITA and Biocompatible team! Best of all you are now going to make a tremendous amount of money!!"**

98. The Relator and other sales staff members were instructed to learn and memorize all of the information presented to them at the July 2006 meeting. Relator studied all of the material including the Launch Packet to understand all of the information in the studies that were

presented to him. When he returned to his sales territory (New England) he was able to promote LC Bead for drug eluting chemoembolization very effectively. Due to this promotion, by the end of 2006 the Relator successfully sold $141,445 in LC Bead to:

a. Brigham and Women's Hospital; $35,000

b. Hartford Hospital; $28,710

c. Maine Medical Center; $9,570

d. Massachusetts General Hospital; $17,000

e. Mercy Hospital in Maine; $9,570

f. Morton Hospital; $3,885

g. Rhode Island Hospital; $7,770

h. Roger Williams Medical Center; $10,800

i. Saints Memorial Hospital; $9,570

j. St. Vincent Hospital; $3,190

k. West Roxbury VA Medical Center; $6,380

99. The sales pitch that Relator provided to physicians and hospitals at the instruction of BIOCOMPATIBLES and RITA, which allowed him to successfully sell LC Bead to the aforementioned hospitals, included presenting LC Bead to interventional radiologists as (1) a drug-eluting bead that had been approved for embolization in the United States and for drug-loading in Europe, when it now appears that both of these statements were known by BIOCOMPATIBLES and RITA to be false; (2) that LC Bead allows for less systemic exposure of the drug than cTACE, therefore, patients will experience fewer side effects and more drug exposure to the tumor, which will result in better tumor response rates; (3) that LC Bead loads drug through an ionic exchange mechanism, with LC Bead having a negative ionic charge due to

the high percentage (45%) of AMPS in the bead and is able to bind to certain positively charged chemotherapeutic agents, such as doxorubicin, because the positively charged doxorubicin molecule is attracted to the negatively charged AMP molecule and binds to the bead; and (4) that when LC Bead is injected into the tumor the blood molecules slowly push the drug out of the bead and into the tumor.

100. One example of this was Maine Medical Center. The Interventional Radiology department at Maine Medical Center asked Relator to come to a meeting of the entire Interventional Radiology department, which included doctors, nurses and techs, to present LC Bead to the group. Bliss spoke before the group and described how LC Bead is able to load and elute doxorubicin through an ionic exchange mechanism and that this would enable their patients to have less systemic exposure to the drug, therefore fewer complications, and a greater drug concentration in the tumor, which should lead to a better tumor response rate. After his presentation the Interventional Radiology department at Maine Medical Center began purchasing and using LC Bead for their HCC patients. Paul Shea, Vice President of Sales at ANGIODYNAMICS, was with Relator at this presentation in the fall of 2006.[8]

101. The Relator and other RITA sales reps would actually train the hospital pharmacists on how to load the LC Bead with chemotherapy drugs. They told the pharmacist that LC Bead is the exact same product as DC Bead, and the Relator would then give the pharmacist the DC Bead drug loading instruction sheet from the BIOCOMPATIBLES website, so that the pharmacist could follow the step-by-step instructions for loading LC Bead with doxorubicin. One example of this was when the Relator trained Jennifer Ferolito, the Cancer Pharmacist at

[8] Although RITA held the distributorship for LC Bead at this time, Shea was doing due diligence for ANGIODYNAMICS' potential acquisition of RITA and requested that he be allowed to accompany the Relator on some of his customer visits to observe how the Relator sold RITA products.

Rhode Island Hospital, on how to properly load doxorubicin onto LC Bead in the pharmacy. Ms. Ferolito was very receptive to this information and appreciated that he was able to instruct her in how to do this.

102. On or about December 8, 2006, BIOCOMPATIBLES created a document entitled "LC Bead IFU" (Instructions for Use), that was given to the RITA sales force so that they could share it with customers when asked for instructions for using LC Bead. That document, a copy of which is in the Relator's possession, states that "***LC Bead microspheres are intended to be used for the embolisation of hypervascular tumors and arteriovenous malformations (AVMs)***," but this marketing statement was clearly untrue as the document itself provides instructions for drug loading, an entirely different "intended use."

103. The Relator also requested a customer and friend, Dr. Christopher Binkert of Brigham & Women's Hospital, to speak to other physicians in his territory about the success that he was having when using LC Bead loaded with drug. Dr. Binkert was an Interventional Radiologist at Brigham and Women's Hospital in Boston who developed considerable experience with LC Bead loaded with drug and was willing to speak with other physicians about his positive experience with LC Bead. For example, Relator had a meeting with Dr. Greg Soares, who is an Interventional Radiologist at Rhode Island Hospital. Dr. Soares was receptive to the sales messaging that the Relator presented to him about LC Bead, but he wanted to speak with someone who had experience using LC Bead. The Relator called Dr. Binkert on his cell phone and he spoke with Dr. Soares about his experience with LC Bead. Following this phone conversation Dr. Soares decided that he wanted to try LC Bead and purchased the product for an upcoming case.

104. The Relator presented studies and abstracts about LC Bead to physicians and hospital employees. The Relator recalls that study and abstract presentation was a very powerful way to get interventional radiologists to start using LC Bead. The studies and abstracts that he was trained to present to physicians included:

a. **DC Bead: In Vitro Characterization of a Drug-delivery device for Transarterial Chemoembolization.**[9] The Relator used this study to tell physicians and pharmacists how LC Bead is able to load and elute doxorubicin in a controlled manner and how much drug can be loaded and how long it takes.

b. **New Intra-arterial Drug Delivery System for the Treatment of Liver Cancer: Preclinical Assessment in a Rabbit Model of Liver Cancer.** The Relator used this paper to show how LC Bead loaded with doxorubicin has low systemic exposure of the drug and a high tumor concentration of the drug, which should result in less toxicity and complications and a better tumor response.

c. **Chemoembolization of Hepatocellular Carcinoma with drug eluting beads reduces the systemic availability of doxorubicin. A pharmacokinetic assessment.** The Relator used this poster to tell physicians that LC Bead will allow for a reduction of drug related toxicity for their patients.

BIOCOMPATIBLES and ANGIODYNAMICS (2007-2011)

105. ANGIODYNAMICS purchased RITA Medical Systems on January 29, 2007, and took over RITA's exclusive distribution agreement for LC Bead, retaining most of the sales staff, including Relator. Mr. Bliss worked for ANGIODYNAMICS from January 2007 until July

[9] This study, conducted at the School of Pharmacy and Biomolecular and Science University of Brighton Essex, United Kingdom in 2005. Several of the authors are identified as being employed by Biocompatibles. This was not an animal or human study.

2008. Relator was the Global Product Manager, RFA Devices in the Oncology Division for ANGIODYNAMICS.

106. During Relator's time at ANGIODYNAMICS, the LC Bead continued to be sold in the same fashion as it was in 2006 under RITA and Relator believes these practices continued until ANGIODYNAMICS lost its distributorship for LC Bead on December 31, 2011. Although Relator was not directly involved with the sales of LC Bead, he has direct knowledge through observation that none were sold for use without chemotherapy agents; all were sold and used as drug eluting beads. In addition to written marketing materials that demonstrate this focus, Relator observed company sales reps and management directly market, promote and sell the product for use with chemotherapeutic drugs to physicians and hospitals.

107. In addition to the practices described above, ANGIODYNAMICS would also pay physicians who were involved in its Oncology Referral Program. The amounts were between $1,000 and $2,000 and the purpose was to promote use of the LC Bead as a drug eluting device to treat HCC and metastatic colorectal cancer. The stated goal was to engage physician customers who had a lot of experience using the LC Bead to present on the benefits of the product in order to increase sales.

108. One example of this was a speaker event that took place on May 6, 2008, in which Dr. David Riggans gave an ANGIODYNAMICS sponsored dinner lecture about LC Bead and RFA to the Interventional Radiologists from the Medical Center of Georgia. Dr. Riggans was paid $1,500 to give this lecture by ANGIODYNAMICS on behalf of BIOCOMPATIBLES. The Oncology Referral Program (ORP) speaker board members consisted of physicians whose names were submitted by the sales team as Key Opinion Leaders that perform a lot of procedures using

ANGIODYNAMICS products and would be persuasive at convincing other physicians to use ANGIODYNAMICS products.

109. On or about January 18, 2008, BIOCOMPATIBLES created a presentation entitled "Precision TACE" to give to the ANGIODYNAMICS sales force to train them on LC Bead. This document in the Relator's possession states on slide #3 that "***LC Bead is indicated for the embolisation of AVMs and hypervascularized tumors.***" This marketing statement was fraudulent because BIOCOMPATIBLES knew or should have known that LC Bead had no FDA clearance or approval whatsoever at this time. The BIOCOMPATIBLES product cleared by the FDA was Bead Block, a totally different product distributed by Terumo.

110. On or about June 4, 2008, ANGIODYNAMICS created a presentation entitled ***"LC Beads Physician Presentation"*** *which* was used by ANGIODYNAMICS' physician customers to make presentations to referring physicians about LC Bead to increase their patient referrals for LC Bead cases. On slide #21 of this presentation it is stated that "***LC Bead was designed as a drug-eluting bead that combines pharmaceutical and medical device technology to produce a device which has the potential to be more effective than either technology on its own.***" This clearly indicates that BIOCOMPATIBLES designed LC Bead as a combination product intended for drug loading. On slide #23 of this presentation it is stated that ***"LC Bead is cleared by the FDA for the embolization of hypervascularized tumors and arterial venous malformations (AVMs)."*** This marketing statement was fraudulent because ANGIODYNAMICS knew or should have known that LC Bead had no FDA clearance or approval whatsoever at this time.

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BIOCOMPATIBLES and BTG (2011 to Present)

111. BTG acquired BIOCOMPATIBLES on January 11, 2011, largely because of the strength of its sales of drug-eluting beads in the United States and Europe. Relator was hired by BTG/BIOCOMPATIBLES in September of that year in anticipation of the December 31st expiration of ANGIODYNAMICS's exclusive U.S. distribution agreement for LC Bead.

112. Although BTG has been more cautious than BIOCOMPATIBLES, RITA and ANGIODYNAMICS previously were about the use of written materials that blatantly promote BIOCOMPATIBLES' drug-eluting beads off-label for their intended use as a drug delivery device, BTG's efforts at compliance can only go so far because its predecessors were very successful in establishing chemotherapeutic drug elution as the sole market for the LC Bead in the United States.

113. BTG/BIOCOMPATIBLES' written training materials for sales representatives are called the Articulate 6 of the Biocompatibles Bead Block/LC Bead Learning System. On page one, the document states "…Drug loading is not an indication in the United States…" However, on page 17 it states: "LC Bead and DC Bead are identical products that have different indications….however in the United States, LC Bead and LC Bead M1 are indicated only for the embolization of hypervascular tumors and AVM's. Physicians will ask you questions about loading beads with chemotherapeutic agents and Articulate 8 will prepare you to answer them. Because DC Bead is approved for drug loading outside the United States, this section will refer to DC Bead. This section will introduce you to loading DC Bead with chemotherapeutic agents…"

114. On page 60 the document discusses LC Bead product characteristics for MSL (Medical Science Liaison) but concedes that the data is from clinical practice and scientific

research using DC Beads in Europe. As such, the company sales force is trained to understand and convey how the LC Bead is used for transporting chemotherapeutic agents based on its testing and use in Europe.

115. BIOCOMPATIBLES' Promotional Review Committee (PRC"), which approves all marketing materials, has become more cautious since the BTG acquisition in January, 2011, and will not allow use of titles to articles describing off-label use of the LC Bead as a drug delivery device, even though the members of the committee are completely aware that the product is being marketed solely as a chemotherapy eluting bead. Any marketing project (including brochures, advertisements, case studies, materials and exhibits for conferences) must be reviewed and approved by the BTG/BIOCOMPATIBLES Promotional Review Committee (PRC).

116. The PRC is made up of approximately eleven individuals who work for BTG or BIOCOMPATIBLES and each person must separately give his/her written approval to the use of all marketing materials. The individuals on the Committee include: 1) James Glasgow V.P. Field Medical and BTG Medical Director; 2) Alistair Taylor, Director of Regulatory Affairs, Biocompatibles; 3) Gabriel Holdsman, Vice President and General Counsel U.S., BTG; 4) Guenter Janhofer, Chief Medical Officer and Head of Development, BTG; and 5) Jeff Klimaski, VP of Compliance.

117. The PRC adopts the position that as long as marketing and promotional materials do not contain information about the fact that the LC Beads, with annual sales of $30+ million in the U.S., are used solely to deliver chemotherapy drugs as a drug eluting bead, then the company is compliant with FDA marketing regulations.

118. BTG/BIOCOMPATIBLES has also set up a Medical Science Liaison ("MSL") team for the ostensible purpose of preventing off-label promotion when the reality is that the liaisons help to sell the product for the off-label use. The Relator knows that some members of the medical staff feel they are directly helping to "sell" the LC Bead for its intended use as a drug-delivery device. For example, Jennifer Rychcik met with Dr. Jeffrey Pollack from Yale New Haven Hospital in 2012 and exclaimed in Relator's presence "I sold LC Bead M1 to Dr. Pollack!" Sam Haddad, New England sales representative for BIOCOMPATIBLES, has also witnessed Jennifer Rychcik making this statement multiple times.

119. The company has ostensibly set up this MSL team to seek to handle the issue of off label promotion of the LC Beads. There were initially ten members on the team, but two quit (Claire Jennings of Jamaica Plain, Massachusetts and Beth Ramer from near Philadelphia, Pennsylvania). The MSL team purports to be entirely separate from the sales team so that medical information can be conveyed to physicians asking for specific data on LC Beads and their use with chemotherapy drugs by a non-sales person. However, this is really a sham as the product is marketed, sold and promoted off label to the physicians by the sales force and the MSL team has in reality become an arm of the sales team.

120. The Relator has also observed the company's high level officials speak openly to physicians and others at various events as noted:

a. John Sylvester – Chief Commercial Officer at BTG/BIOCOMPATIBLES. Clinical Interventional Oncology (CIO) Medical Society Conference in Miami FL January 18-19, 2013. Only the Medical Affairs team is permitted at BIOCOMPATIBLES to answer off-label questions by physicians about its products. At CIO Sylvester spent approximately one hour speaking with various

U.S. physicians about off-label information about LC Bead (drug loading, studies). The Relator witnessed this as well as Lindsey Raymond, the Trade Show Events Coordinator.

b. Lance Funderburk – Regional Sales Manager, Southeast, at BTG/BIOCOMPATIBLES. Clinical Interventional Oncology (CIO) Medical Society Conference in Miami Florida January 18-19, 2013. Funderburk said to the Relator: "when a physician brings up off-label topics I just go off label." The Relator knew that meant the discussions all related to use of the product with chemotherapy as a drug eluting bead.

121. The sales incentive plan also causes reps to push the product off-label. Sales reps must earn 100% of last year's earnings plus 10-15% in order to enjoy the incentives. Since the entire market in the United States for LC Bead is for drug elution, the representatives cannot meet their prior year's sales, much less increase them by 10-15%, without promoting the device for off-label use.

D. THE FALSE CLAIMS ACT

122. The False Claims Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 to $11,000 for each such claim, plus three times the amount of the damages sustained by the Federal Government. 31 U.S.C. § 3729 (a); Federal Civil Monetary Penalties Inflation Adjustment Act of 1990, Pub. L. 101–410; 64 FR 47099, 47104 (Aug. 30, 1999).

123. The Act allows any person having information about false or fraudulent claims to bring an action for himself and the Government and to share any recovery. 31 U.S.C. § 3730 (b). The Act requires that the complaint be filed under seal for a minimum of sixty days without service on the defendant during that time. *Id.* The states listed in the caption have state-law counterparts to the False Claims Act with similar provisions.

124. Based on these provisions, *qui tam* Relator Bliss seeks through this action to recover damages and civil penalties arising from Defendants' knowing fraud on the federal and governments.

E. LC BEAD IS NOT REIMBURSABLE & CLAIMS FOR ITS USE ARE FALSE OR FRAUDULENT CLAIMS

Reasonable & Necessary Standard

125. Medicare is not permitted to pay for any expense that is not "reasonable and necessary for the diagnosis and treatment of illness or injury." 42 U.S.C. § 1395(a)(1)(a). Similarly, state Medicaid plans generally restrict coverage to reasonable and necessary medical expenses. Also, TRICARE, the military managed care program, excludes coverage for "services and supplies that are not medically or psychologically necessary. . . ." TRICARE Policy Manual, Section 1.2. CHAMPVA is believed to have a similar restriction.

126. Agency interpretations of the "reasonable and necessary" standard generally exclude coverage for drugs and devices that have no FDA approval whatsoever as they cannot be legally marketed or used for any purpose (making their use to treat patients unreasonable), and limit reimbursement for approved drugs and cleared or approved devices to their FDA-approved indications and any off-label uses that are medically proven as safe and effective. Mem. From Thomas A. Ault to All Regional Administrators, re: *Medicare Coverage of Investigational Devices,* p. 1 (Dec. 28, 1994) ("Medicare has historically interpreted the statutory terms

"reasonable and necessary" to mean that a service must be safe and effective, and not experimental.")

127. Because LC Bead had no approval whatsoever between April 17, 2006, (when Biocompatibles launched LC Bead) and December 24, 2008, (when Biocompatibles fraudulently obtained a 510k clearance for LC Bead from the FDA), use of LC Bead during this period by healthcare providers at the urging of the Device Defendants was not "reasonable" and was not subject to coverage and reimbursement by government healthcare programs. Accordingly, all claims for such reimbursement that the Device Defendants knowingly caused healthcare providers to submit were false or fraudulent claims within the meaning of the False Claims Act and its state law counterparts.

128. Also, since the clearance of LC Bead on December 24, 2008, was obtained fraudulently, use of LC Bead after that date has not been "reasonable" and government healthcare programs would not have provided coverage and reimbursed for that use had they known of the fraudulent misrepresentations and failures to disclose material facts that led to the FDA clearance. Accordingly, all claims for such reimbursement were false or fraudulent claims which the Device Defendants knowingly caused to be submitted, whether the healthcare providers submitting the claims knew of Biocompatibles' fraud or not.

129. Moreover, even if LC Bead had not been fraudulently cleared for marketing, use of doxorubicin and irinotecan with LC Bead to treat liver cancer in the DEBTACE procedure is an off-label use of both the drugs and the devices that has not been demonstrated to be safe and effective and for which government healthcare programs have not made an affirmative coverage determination or individual coverage decisions of "reasonableness and necessity" following disclosure of the experimental DEBTACE procedure in which the drugs and devices have been

used. Accordingly, off-label use of the drugs and devices by healthcare providers is not subject to reimbursement by government healthcare programs and all claims for such reimbursement were false or fraudulent claims which the Device Defendants knowingly caused healthcare providers to submit.

Drugs Used Off-Label

130. In addition to the "reasonable and necessary" restriction, Medicare and Medicaid reimbursement for drugs is statutorily limited to "covered outpatient drugs." 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2), (3). Covered outpatient drugs are drugs that are used for "a medically accepted indication." *Id.*, § 1396r-8(k)(3). A medically accepted indication may either be a use which is listed in labeling approved by the FDA, or which is supported by one of the drug compendia identified in the Medicaid statute. *Id.*, § 1396r-8(k)(6). TRICARE limits reimbursement for drugs to "those drugs . . . treatments, or procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies." TRICARE Policy Manual, Section 2.1. A drug, treatment or procedure is considered unproven "unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis." Id. CHAMPVA is believed to have similar coverage restrictions.

131. Use of doxorubicin and irinotecan for treatment of liver cancer by means of drug-eluting beads is neither listed in the drugs' FDA approved labeling, supported by listings in the medical compendia, nor "proven" by well-controlled studies. Therefore, these drugs are not reimbursable by government healthcare programs when used in the DEB TACE procedure.

Accordingly, all claims for such reimbursement that Device Defendants knowingly caused healthcare providers to submit were false or fraudulent claims.

Devices Used Off-Label

132. Medicare permits its administrative contractors to use "contractor discretion" to provide reimbursement for off-label uses of approved or cleared medical devices after making a determination that the off-label use is safe and effective. Mem. From Thomas A. Ault to All Regional Administrators, re: *Medicare Coverage of Investigational Devices,* p. 6 (Dec. 28, 1994) (hereinafter "Ault Memorandum") ("An approved or cleared device may be covered by Medicare for a labeled indication and, based on contractor discretion, for an unlabeled use as long as this does not conflict with FDA requirements. For example, an approved cardiac catheter, whose label only includes a diagnostic indication, may be covered by a contractor for an unlabeled therapeutic indication, based on the contractor's determination that the unlabeled use is safe and effective."); *U.S. ex rel. Colquitt v. Abbott Laboratories*, 864 F. Supp. 2d 499, 531 (N.D. Tex. 2012), reconsideration denied (Aug. 24, 2012) (Citing Ault Memorandum).

133. "[A]bsent an affirmative determination of safety and effectiveness by a contractor, off-label use of a cleared or approved device is not covered by Medicare." *Colquitt, Id*, at p. 533. Because the billing codes promoted to healthcare providers by the Device Defendants and actually used by the healthcare providers to bill government healthcare programs were false and misleading, government contractors have never known that LC Bead is used off-label in the DEBTACE procedure and therefore they have made no affirmative determination of its safety and effectiveness for this off-label use.

134. Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered. 42 C.F.R. § 405.207. These excluded services include all

services furnished in preparation for the use of a non-covered device, services furnished contemporaneously with and necessary to the use of the non-covered device, and services furnished as necessary after-care that are incident to recovery from the implantation of the device. *Id.*

135. Similarly, TRICARE restricts reimbursement to "devices, treatments, or procedures for which the safety and efficacy have been proven . . . ." TRICARE Policy Manual, Section 2.1. "A . . . device, medical treatment, or procedure is unproven . . ."[i]f the reliable evidence shows that the consensus among experts regarding the medical treatment or procedure is that further studies or clinical trials are necessary to determine its . . . safety, or its effectiveness as compared with the standard means of treatment or diagnosis." *Id.* "This exclusion includes all services directly related to the unproven . . . device, medical treatment or procedure." *Id.*

136. The TRICARE Policy Manual further states that "[a]pproval for reimbursement of off-label uses of devices shall be provided by the contractor. The contractor may provide approval for the reimbursement of off-label uses when the off-label use is medically necessary and demonstrations from medical literature, national organizations, or technology assessment bodies show that the off-label use of the device is safe, effective and in accordance with nationally accepted standards of practice in the medical community. If the device is FDA approved and the off-label use is medically necessary, supported by medical literature identified by the contractor, which indicates the device is nationally accepted as standard practice, and is not otherwise excluded, the contractor may approve the cost-sharing for the off-label medical device." TRICARE Policy Manual Chap. 8 § 5.1, 2.3.2. CHAMPVA is believed to have similar coverage restrictions.

137. Because the safety and efficacy of the off-label use of LC Bead in the DEBTACE procedure have not been demonstrated, and because no national, local or individual coverage determinations have been made by any government healthcare system (based upon an accurate disclosure of the use being made of the LC Bead), off-label use of LC Bead in the DEBTACE procedure is not covered or subject to reimbursement under government healthcare programs. Accordingly, all claims for such reimbursement that Device Defendants knowingly caused healthcare providers to submit were false or fraudulent claims.

Devices Used Without FDA Clearance or Approval

138. Absent exceptions not relevant to this case, federal regulations prohibit Medicare coverage for experimental or investigational devices. 42 C.F.R. § 411.14(o); *Colquitt, supra,* at p. 531. A device is experimental or investigational if it has not been approved by the FDA through the premarket approval process or the 510(k) clearance process. *Id.*

139. As stated in the Ault Memorandum, quoting Medicare manuals extant prior to 1995, "Medical devices which have not been approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures or services using devices which have not been approved for marketing by the FDA." Ault Memorandum, p. 1. As further stated in the Ault Memorandum, "[t]his longstanding policy, which is binding on our contractors, explicitly excludes from coverage devices, and services using devices, that have not been approved for marketing by the FDA. This policy applies to any

device that is subject to FDA review. The Medicare manuals do not allow any exceptions to this policy." *Id.*[10]

140. Similarly, TRICARE provides coverage only for "devices, treatments, or procedures for which the safety and efficacy have been proven," TRICARE Policy Manual, Chap. 1, §2.1, 1.0, and a device, medical treatment or procedure is considered unproven "[i]f the . . . device cannot be lawfully marketed without the approval or clearance of the U.S. Food and Drug Administration (FDA) and approval or clearance for marketing has not been given at the time the drug or device is furnished to the patient." *Id,* at 2.1. Furthermore, the TRICARE Policy Manual states explicitly that "[m]edical devices must be FDA approved or of a type not requiring pre-market approval by the FDA." *Id,* at Chap. 8, §5.1, 2.2. CHAMPVA is believed to have similar restrictions on coverage.

141. Because LC Bead had no approval whatsoever between April 17, 2006, (when Biocompatibles launched LC Bead) and December 24, 2008, (when Biocompatibles fraudulently obtained a 510k clearance for LC Bead from the FDA), use of LC Bead during this period by healthcare providers at the urging of the Device Defendants was not subject to coverage and reimbursement by government healthcare programs. Accordingly, all claims for such

[10] Prior to 1995, this policy applied not only to wholly uncleared and unapproved devices, but also to devices that had been granted an investigational device exemption ("IDE") by the FDA for use in clinical trials to establish their safety and efficacy. As applied to IDE devices between 1986 and 1995, this policy was held to be arbitrary and capricious in *Yale-New Haven Hospital v. Leavitt*, 470 F.3d 71 (2d Cir. 2006). In 1995, Medicare adopted regulations providing an IDE exemption to its policy excluding coverage for experimental or investigational devices, *see Criteria and Procedures for Extending Coverage to Certain Devices and Related Services,* 60 FR 48417-01, so the *Leavitt* decision is of limited applicability to the IDE devices during the period 1986-1995.

The IDE exemption is inapplicable in this case because Biocompatibles did not obtain an IDE for use of LC Bead in clinical trials, but rather marketed it for general use from 2006 until late 2008 with no FDA clearance, approval or IDE exemption whatsoever and from late 2008 until the present with an FDA clearance that was fraudulently obtained.

reimbursement that the Device Defendants knowingly caused healthcare providers to submit were false or fraudulent claims within the meaning of the False Claims Act.

142. Also, since the clearance of LC Bead on December 24, 2008, was obtained fraudulently, government healthcare programs would not have provided reimbursement for use of the device had they known of the fraudulent misrepresentations and failures to disclose material facts that led to the FDA clearance. Accordingly, all claims for such reimbursement were false or fraudulent claims which the Device Defendants knowingly caused to be submitted, whether the healthcare providers submitting the claims knew of Biocompatibles' fraud or not.

F. THE DEVICE DEFENDANTS MISLED HEALTHCARE PROVIDERS AND KNOWINGLY CAUSED THEM TO SUBMIT FALSE CLAIMS

143. From the inception of LC Dead's product launch in the United States in 2006, the Device Defendants have emphasized that LC Bead and DC Bead are the same product and have falsely suggested that Biocompatibles' drug-eluting beads should be considered safe and effective because they received the approval of European regulators, when in truth and in fact, DC Bead received nothing more than a certificate of conformity (CE mark) issued by a private testing firm and the only Biocompatibles product actually evaluated for safety and effectiveness by regulators in the European Union, the PRECISION Bead pre-loaded with doxorubicin, was denied approval. Therefore, the entire gist of the Device Defendants' U.S. marketing campaign for LC Bead was false and misleading.

144. Moreover, from April 17, 2006, (when Biocompatibles launched LC Bead) until December 24, 2008, (when Biocompatibles fraudulently obtained a 510k clearance for LC Bead from the FDA), Biocompatibles and RITA falsely represented to healthcare providers that LC Bead had a 510k clearance from the FDA, when in truth and in fact the product cleared by the FDA was Bead Block, a bland embolization device that was not capable of loading and eluting

drugs and was both designed and marketed for an entirely different use in treating uterine fibroid tumors without chemotherapy.

145. By falsely promoting LC Bead as a safe and effective device cleared by the FDA for general marketing and approved by European regulators for use in the DEBTACE procedure, the Device Defendants knowingly caused healthcare providers to purchase more LC Bead, doxorubicin and irinotecan than they otherwise would have purchased; to perform more off-label DEBTACE procedures than they otherwise would have performed; and to bill government healthcare programs for vastly more off-label and non-reimbursable uses of LC Bead and the drugs than they otherwise would have billed.

146. Had healthcare providers known (1) that LC Bead was wholly un-cleared and unapproved in the United States until December 24, 2008, (2) that the FDA clearance in 2008 was obtained by fraud and (3) that the European Union denied approval for the exact same bead product preloaded with doxorubicin in 2008 because it was not found to be sufficiently safe and effective, then those healthcare providers would not have submitted false claims to government healthcare programs for non-reimbursable DEBTACE procedures utilizing a wholly unapproved or fraudulently cleared device the safety and efficacy of which has not been demonstrated.

147. Furthermore, the Device Defendants provided reimbursement advice to healthcare providers suggesting that they bill federal and state healthcare programs for treatment of patients using LC Bead, doxorubicin and irinotecan in the DEBTACE procedure under CPT codes and HCPCS "J" codes falsely suggesting that the treatment provided was the TAE or cTACE procedure and providing no notice whatsoever that the billed procedure was actually a new and experimental procedure requiring a coverage determination.

148. For physician services billed to Medicare Part B, Medicaid, TRICARE and CHAMPVA, CPT procedure codes and HCPCS "J" codes for injectable drugs are listed by the physician in Section 24 of the CMS 1500 billing form. For hospital services billed to Medicare Part A, Medicaid, TRICARE and CHAMPVA, the CPT procedure codes are listed by the hospital in Section 74 and the HCPCS "J" codes for injectable drugs are listed in Section 24 of the CMS 1450 billing form.

149. The CPT procedure code that has been promoted by the Device Defendants is CPT Code 37204, which is described as "[t]ranscatheter occlusion or embolization (eg, tumor destruction, achieve hemostasis, occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head/neck." As noted above in Section A of this Complaint, this CPT code describes the traditional TAE procedure and arguably the cTACE procedure, both of which utilize bland embolic beads like Bead Block to occlude blood flow to a tumor. This CPT code does not describe the DEBTACE procedure using a drug-eluting bead like LC Bead because the endpoint for the DEBTACE procedure is continued blood flow to the tumor in order that drug eluted from the beads will be carried into the tumor over a period of 14 days and so that the beads themselves will not be refluxed into the circulatory system.

150. The HCPCS "J" code promoted by the Device Defendants is J9000 (Injection, doxorubicin hydrochloride, 10 mg), which describes an injection of doxorubicin, something that occurs in the cTACE procedure, but does not occur in the DEBTACE procedure, where the drug is eluted from a drug-eluting bead rather than being injected through a catheter at the site of the tumor. The combination of this "J" code with the 37304 CPT code falsely suggests that the healthcare provider has performed the cTACE procedure, which has been medically accepted for

30 years, when in fact the procedure performed is the DEBTACE procedure, which is an investigational procedure that has been the subject of experimentation only since 2002.

151. CPT codes are created and copyrighted by the American Medical Association ("AMA"). The instructions that accompany the CPT Manual published by the AMA state that providers should "not select a CPT code that merely approximates the service provided." Rather, if no accurate service procedure or service exists among the standard CPT codes, providers are instructed to "report the service using the appropriate unlisted procedure or service code" (i.e. the special CPT codes provided for use when none of the standard CPT codes reasonably and adequately describes the specific procedure or service provided). Codes listed after each subsection of the CPT Manual and ending in -99 or -9 are "unlisted" codes.

152. As new medical procedures become accepted by the medical profession, the AMA adds new codes to the CPT Manual to replace the "unlisted" procedure codes. A 17-member CPT Editorial Panel meets three times a year to consider proposals for addition of codes to the CPT Manual and is assisted by a CPT Advisory Committee made up of representatives of over 100 medical specialty societies and other health care professional organizations. The AMA provides a Coding Change Request Form and instructions for its use by individuals, physicians and specialty groups in submitting requests for new CPT codes. The acceptance of new codes is generally based upon the procedure being consistent with contemporary medical practice and being performed by many physicians in clinical practice in multiple locations. In developing new and revised CPT codes the Advisory Committee and the Editorial Panel requires that the service/procedure receive approval from the Food and Drug Administration (FDA) for the specific use of devices or drugs, that the service/procedure is performed across the country in multiple locations, that many physicians or other health care professionals perform the

service/procedure; and that the clinical efficacy of the service/procedure has been well established and documented.

153. Thus, the AMA acts as a gatekeeper to the reimbursement system of government healthcare systems by declining to establish CPT codes for experimental or investigational medical procedures that involve a "specific use" of a device or drug that is off-label in the sense that it has not yet been approved by the FDA. When a physician submits a billing to a government healthcare program's contractor for an "unlisted" code, he thereby alerts the contractor that it must make an individualized determination whether the service is properly reimbursable.

154. The DEBTACE procedure using LC Bead loaded with doxorubicin or irinotecan has no specific CPT code assigned to it and should be billed using an "unlisted" code to identify it as an experimental procedure for which the AMA has not yet created a CPT code because it is not yet generally accepted and involves an off-label use of drugs and devices. For example, CPT Code 37999 (unlisted procedure, vascular surgery) is in the same Cardiovascular Surgery section of the CPT Manual with CPT 37204, but would alert government contractors that this is not the traditional embolization procedure described by CPT Code 37204, but rather a new and experimental procedure requiring a coverage determination. Alternatively, CPT Code 96549 ("unlisted chemotherapy procedure"), which is in the section of the CPT book dealing with Chemotherapy Administration, would reveal that a new and experimental form of chemotherapy was being performed, again requiring a coverage determination.

155. Because Medicare, Medicaid, TRICARE and CHAMPVA contractors are required to review off-label device claims and make a determination whether an off-label use is safe and effective before providing reimbursement for procedures utilizing the device, healthcare

providers should have provided accurate coding information utilizing the "unlisted" procedure codes so that the contractors could make informed payment decisions. By encouraging providers to hide the true nature of the DEBTACE procedure using the CPT code for traditional TAE embolization procedures, the Device Defendants have knowingly caused the submission of false claims for non-reimbursable procedures.

156. Also, because Medicare, Medicaid, TRICARE and CHAMPVA do not provide coverage for off-label uses of drugs such as doxorubicin and irinotecan unless they are supported by applicable compendia as medically-accepted off-label uses, healthcare providers should not have billed the "J" code for "injection" of doxorubicin when in fact it was not administered by means of an intravenous injection, but instead was administered by drug-eluting beads. By encouraging providers to hide the true route of administration of the drug in the DEBTACE procedure by using the "J" code for intravenous injections, the Device Defendants have knowingly caused the submission of false claims for non-reimbursable drugs.

157. The false procedure and drug coding was material to the payment decisions of government contractors because procedure and drug codes are utilized in making coverage and payment decisions for all government healthcare programs, including specifically the Prospective Payment System of Medicare Part A, and have a natural tendency to affect the government programs' payment decisions.

158. With respect to Medicare Part A and other government healthcare programs that make flat-fee or bundled payments, although CMS makes a bundled DRG payment based upon the "diagnosis related group" to which each patient's treatment is assigned, the procedure codes listed on the CMS 1450 billing form are an important factor taken into consideration in

determining the applicable DRG. *See* 42 C.F.R. § 412.60(c)(1).[11] Therefore, the codes billed on Form 1450 would have a natural tendency to affect coverage and payment decisions of government healthcare programs and are material to those decisions.

G. THE HOSPITAL DEFENDANTS KNOWINGLY SUBMITTED FALSE CLAIMS

159. Although the Hospital Defendants received reimbursement advice from the Device Defendants and were caused to bill false CPT and "J" codes by the advice they received, the Hospital Defendants also knew or should have known of the falsity of the billing codes they used. The Hospital Defendants either acted with actual acknowledge that the CPT and "J" codes used to bill DEBTACE to government healthcare programs were false or they acted with reckless disregard or in deliberate ignorance of the truth or falsity of the codes used in their billings.

160. Accordingly, the Hospital Defendants are also guilty of knowingly submitting false claims to government healthcare programs.

H. INDICIA THAT FALSE CLAIMS WERE ACTUALLY SUBMITTED TO GOVERNMENT HEALTHCARE PROGRAMS

161. Liver cancer is a disease that disproportionately affects elderly populations insured by Medicare. The median age of patients diagnosed with primary liver cancer is 63 and 45.8% of patients diagnosed with the disease are 65 or older.[12] The median age at death from

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[11] 42 C.F.R. § 412.60(c) states in part that:
"**(c) Assignment of discharges to DRGs.** CMS establishes a methodology for classifying specific hospital discharges within DRGs which ensures that each hospital discharge is appropriately assigned to a single DRG ***based on essential data abstracted from the inpatient bill*** for that discharge.
(1) The classification of a particular discharge is based, as appropriate, on the patient's age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient's admission to the hospital), secondary diagnoses, ***procedures performed***, and discharge status." (Emphasis added.)
Therefore, the procedures performed by the hospital, as listed on the patient's inpatient bill on form CMS 1450, is a factor taken into consideration by the Medicare contractor in making its payment decision.

[12] *See* http://seer.cancer.gov/statfacts/html/livibd.html (last visited July 17, 2013).

primary liver cancer is 68 and 57.6% of deaths from the disease occur in persons age 65 or older.[13]

162. The median age of patients diagnosed with colorectal cancer (which can spread to the liver in mCRC) is 68 and 60.1% of patients diagnosed with the disease are 65 or older.[14] The median age at death from colorectal cancer is 74 and 70.9% of deaths from the disease occur in persons age 65 or older.

163. Primary liver cancer occurs mostly in men with a history of alcohol or drug abuse, which can lead to liver scarring (cirrhosis) or hepatitis C infections, the primary causes of liver cancer in the United States.[15] Among men, the death rate from liver cancer per 100,000 population is 7.6 for whites, 11.8 for blacks, 14.4 for Asians, 13.2 for native Americans and 12.3 for Hispanics.[16] The median incidence of death from liver cancer that can be calculated for minority men from these figures is 12.75 deaths per 100,000 population, a rate that is 1.67 times that for whites. Nationally, minorities make up 58% of the population served by Medicaid,[17] largely because minorities tend to be less wealthy and more likely to qualify for Medicaid. In summary, patients treated for liver cancer are largely minority males, who are more likely than white males to be Medicaid beneficiaries.

164. Training materials prepared for sales representatives by Biocompatibles and RITA and reimbursement guides provided to physicians and hospitals by all of the Device Defendants included DRG codes that Medicare and Medicaid assign to treatment of liver cancer

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[13] *Id.*
[14] *See* http://seer.cancer.gov/statfacts/html/colorect.html (last visited July 17, 2013).
[15] See http://www.cancer.org/cancer/livercancer/overviewguide/liver-cancer-overview-what-causes (last visited July 17, 2013).
[16] *See* http://seer.cancer.gov/statfacts/html/livibd.html (last visited July 17, 2013).

[17] *See* http://kff.org/medicaid/state-indicator/distribution-by-raceethnicity-4/ (last visited July 17, 2013).

and the amount of the typical reimbursement, indicating that the Device Defendants expected and encouraged the Hospital Defendants to submit claims to Medicare and Medicaid.

165. While the Relator does not have access to HIPPA-protected patient information or the actual patient bills submitted to Medicare and Medicaid by individual physicians and hospitals, he is certain that physicians and the Defendant Hospitals did actually bill Medicare, Medicaid and other government healthcare programs for off-label DEBTACE procedures utilizing the false or misleading CPT and "J" codes promoted by the Device Defendants.

166. Attached hereto as Exhibit B is a spreadsheet containing "call note" case reports by BTG/Biocompatibles sales representatives during the period January 1, 2012, to June 21, 2013, and providing the dates of some of the DEBTACE procedures at issue in this case, the names of the doctors who performed the procedures, the names of the hospitals where the procedures were performed, the names of the sales representatives, and the comments of the sales representative.

167. Charges for the majority of these procedures would have been billed to Medicare or Medicaid within a short time after the dates of the procedures by the physicians who performed the procedures and the Defendant Hospitals where the procedures were performed using the false CPT and "J" codes promoted by BTG/Biocompatibles. Some of these procedures would have been billed to other government healthcare programs like TRICARE and CHAMPVA. While this is not a comprehensive list of procedures billed to government healthcare programs, it provides representative examples of the procedures that were actually performed and billed.

I. THE DEVICE DEFENDANTS SUBMITTED FALSE CLAIMS TO THE DEPARTMENTS OF VETERANS AFFAIRS & DEFENSE

168. The Department of Veterans Affairs ("VA") and the Department of Defense ("DOD") operate nationwide hospital systems that provide healthcare services to veterans and active-duty members of the armed forces. VA and DOD healthcare services are funded by federal appropriations and are provided free-of-charge to eligible veterans and active-duty service members by federally-employed healthcare professionals working at VA and DOD facilities, rather than through a system of health insurance (although some patients at the facilities may also be covered by the military health insurance programs CHAMPVA and TRICARE).

169. VA regulations state that VA healthcare "will be provided to individuals only if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice." 38 C.F.R. § 17.38 (b). The VA regulations also exclude "[d]rugs biologicals, and medical devices not approved by the Food and Drug Administration unless the treating medical facility is conducting formal clinical trials under an Investigational Device Exemption (IDE) or an Investigational New Drug (IND) application, or the drugs, biologicals, or medical devices are prescribed under a compassionate use exemption." 38 C.F.R. § 17.38 (c) (3). DOD regulations are believed to contain similar restrictions and exclusions.

170. The DEBTACE procedure utilizing LC Bead to load and elute doxorubicin or irinotecan is not "a generally accepted standard of medical practice" and neither the drugs nor the device have been approved by the FDA for this use, yet the Device Defendants have sold at least $4.3 million of LC Bead to various VA and DOD hospitals during the most recent 18

months alone (not including sales from 2006-2011), including particularly but not by way of limitation, the 48 VA & DOD hospitals listed on Exhibit C.

171. All of these sales to VA and DOD hospitals, and earlier sales during the period 2006-2001, were procured by means of false and/or misleading statements to VA and DOD personnel by the Device Defendants concerning the regulatory status, safety, efficacy and general acceptance of LC Bead in the medical community, including false and/or misleading statements that failed to disclose the true regulatory status of DC Bead in the European Union, the fraudulent clearance of LC Bead by the FDA in 2008 and the fact of LC Bead's marketing in the United States prior to 2008 without any regulatory clearance or approval whatsoever.

172. Had VA and DOD personnel known the true state of facts, the VA and DOD would not have spent over $4.3 million to purchase LC Bead from the Device Defendants and would not have performed DEBTACE procedures utilizing LC Bead at a cost for related services and facility usage that was at least twice the cost of the devices themselves. Therefore, billing statements for LC Bead that were submitted to VA and DOD hospitals by the Device Defendants on the dates and in the amounts set forth on Exhibit C, plus others submitted during the period 2006-2011, were false or fraudulent claims that have caused damage to the United States in excess of $13 million.

V. PATIENT HARM & RISKS OF UNAUTHORIZED & OFF-LABEL USE

173. Doxorubicin and irinotecan are extremely dangerous drugs. Between November 1997 and August 2012 there have been 4,142 reports to the FDA of a serious adverse event where doxorubicin was identified as the primary suspect drug causing the event and 4,762 reports where irinotecan was identified as the primary suspect drug. In 881 of the doxorubicin events (21%) the patient died. In 1,305 of the irinotecan events (27%), the patient died.

174. The use of these drugs in combination with drug-eluting beads in the DEBTACE procedure for targeted delivery to the liver may possibly decrease the risks of systemic delivery, as the Device Defendants claim, but that assertion has not yet been scientifically proven to the satisfaction of the FDA, which has made no finding of safety and efficacy. Regulatory authorities in the European Union in 2008 refused to approve BIOCOMPATIBLES' PRECISION Bead pre-loaded with doxorubicin, a fact the Device Defendants have attempted to sweep under the rug. There may also be added risks of the DEBTACE procedure over systemic administration of the drugs because the dosage of the drugs administered in the DEBTACE Procedure is usually higher than the approved dosage for systemic administration, there can be unintended damage to the liver and biliary tract, and the drug-loaded beads can migrate to other vital organs where they create life-threatening damage.

175. At least four patients have died in DEBTACE procedures utilizing LC Bead or DC Bead, including:

a. A 31-year-old male in the United States who died on or about August 1, 2011, of pulmonary embolism (a blockage of the main artery of the lung or one of its branches by a substance that has travelled from elsewhere in the body through the bloodstream) after undergoing a DEBTACE procedure using LC Bead to administer doxorubicin;

b. A patient in Greece who died on or about March 18, 2013, of sepsis (a whole-body inflammatory state), hepatic failure (liver failure), encephalopathy (brain injury), cholecystitis (inflammation of the gallbladder), pleural effusion (excess fluid around the lungs), gastrointestinal hemorrhage (intestinal bleeding), pancreatitis (inflammation of the pancreas), ascites (an accumulation of fluid in

the peritoneal cavity) and other acute symptoms after receiving 150 mg of doxorubicin administered by means of DC Bead;

c. A male patient with liver cancer who died on or about November 4, 2009, with a feeling of heat, some coughing and a sudden death (possibly by heart attack) after receiving 50 mg of doxorubicin administered by means of DC Bead;

d. A female patient with liver cancer taking part in a clinical trial who died on or about March 25, 2008, from cardiocirculatory arrest (heart failure) after receiving 100 mg of doxorubicin administered via two vials of DC Bead.

176. These deaths may reflect accidental delivery of high doses of cytotoxic drugs to vital organs such as the heart and lungs through arteriovenous shunting of drug-loaded beads to veins feeding vital organs. Doctors at the Brooklyn Hospital Center have reported a potentially fatal chemoembolization of the lungs of a patient with liver cancer who underwent a DEBTACE procedure using doxorubicin-loaded LC Beads because of an arteriovenous shunt between the hepatic artery and the veins feeding the lungs. *See* Khan et al, "Acute Lung Injury Following Transcatheter Hepatic Arterial Chemoembolization of Doxorubicin-Loaded LC Beads in a Patient with Hepatocellular Carcinoma," LUNG INDIA, 2012 Apr; 29(2): 169-72.

177. There have also been adverse event reports to the FDA of non-fatal but serious and life-threatening events involving the use of doxorubicin and irinotecan in connection with the LC/DC Bead, including:

a. A 74-year-old man in Great Britain who suffered necrotizing pancreatitis (inflammation and tissue death in the pancreas) on or about April 10, 2012, after receiving 75 mg of doxorubicin administered through a DEBTACE procedure using doxorubicin beads;

b. A 55-year-old male in the United States who became unresponsive to stimuli on or about April 25, 2012, after receiving 100 mg of doxorubicin administered intra-arterially using LC Bead;

c. Another 55-year-old man in the United States who suffered acute lung injury on or about September 28, 2012, after receiving 50 mg of Adriamycin (doxorubicin) administered via 100um to 300um beads; and

d. An 83-year-old woman in Italy who suffered chronic obstructive pulmonary disease on or about June 4, 2010, after receiving doxorubicin administered via a DEBTACE procedure.

178. If BIOCOMPATIBLES desires to experiment on patients in the United States using lethal drugs loaded onto beads that can migrate through the circulatory system to vital organs -- with potentially fatal effects -- it should be doing so in the context of the supervised clinical trials that were approved by the FDA in 2005. By refusing to commence those clinical trials because of concerns about money and time to market, BIOCOMPATIBLES has chosen to place its own profits over patient safety. It should be stopped before it causes additional deaths by foisting a fraudulently-cleared product upon an unsuspecting public.

VI. BREADTH AND TIME FRAME OF THE FRAUD

179. Mr. Bliss worked for RITA and ANGIODYNAMICS from November 2005 until July 2008 and for BTG and BIOCOMPATIBLES from September 2011 to the present. The Device Defendants market, promote and sell their products to hundreds of physicians and hospitals in every state of the Union and the Relator has direct knowledge from his sales trainings and sales conference calls with sales directors across the country that the fraudulent techniques described herein were in fact nationwide, companywide practices.

FILED UNDER SEAL

COUNT ONE
VIOLATIONS OF THE FALSE CLAIMS ACT

31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B)
[for violations on or after June 7, 2008]

31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(2)
[for violations prior to June 7, 2008]

180. Relator, acting in the name of and on behalf of the United States, restates and realleges the allegations contained in the preceding paragraphs as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

181. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, as amended.

182. By virtue of the acts described herein, Defendants knowingly presented, or caused to be presented, to officers, employees or agents of the United States under the government healthcare programs, false or fraudulent claims for payment or approval, and made, used and caused to be made and used false records and statements material to false claims for the medical devices and drugs at issue herein.

183. Defendants knew that these claims for payment were false or fraudulent, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard of whether the claims were true or false.

184. Each claim for payment for the use of the drugs and devices constitutes a false or fraudulent claim because the drugs, devices and related services were not covered and reimbursable under government healthcare programs.

185. Each claim for payment for the unauthorized or off-label use of the devices constitutes a false or fraudulent claim because the devices and procedures in question were falsely coded in billings to the government healthcare programs.

186. Unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, and in reliance on the truthfulness and accuracy of certifications made by physicians and hospitals, the United States paid and continues to pay on the claims that would not have been paid but for Defendants' wrongful actions and omissions.

187. The United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

COUNT TWO
VIOLATIONS OF THE FALSE CLAIMS ACT ARISING OUT OF DEFENDANTS' CONSPIRACY TO SUBMIT FALSE CLAIMS

31 U.S.C. § 3729(a)(1)(C)
[for violations on or after June 7, 2008]

31 U.S.C. § 3729(a)(3)
[for violations prior to June 7, 2008]

188. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein.

189. Defendants BIOCOMPATIBLES, RITA and ANGIODYNAMICS in one conspiracy and Defendants BTG and BIOCOMPATIBLES in a second conspiracy combined, conspired, and agreed together with others to defraud the United States by knowingly causing false and illegal claims to be submitted to the United States for the purpose of having those claims paid and ultimately profiting from those false claims. Defendants committed other overt acts set forth above in furtherance of these conspiracies, all in violation of 31 U.S.C. § 3729(a)(3) (2008) and 31 U.S.C. § 3729(a)(1)(c) (2009), causing damage to the United States.

FILED UNDER SEAL

PRAYER FOR RELIEF UNDER THE FEDERAL FALSE CLAIMS ACT

190. Relator respectfully requests this Court to enter judgment against defendants, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and fraud alleged within this Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* provides;

(b) That civil penalties of $11,000 be imposed for each and every false claim that defendants presented or caused to be presented to the United States;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Court grant permanent injunctive relief to prevent any recurrence of violations of the False Claims Act for which redress is sought in this Complaint;

(e) That the Relator be awarded the maximum percentage of any recovery allowed to him pursuant the False Claims Act, 31 U.S.C. §3730(d)(1),(2);

(f) That this Court award such other and further relief as it deems proper.

COUNT THREE

VIOLATIONS OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT

191. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all Defendants conduct business in

the State of Arkansas. Upon information and belief, Defendants' actions described herein occurred in the State of Arkansas as well.

192. This is a qui tam action brought by Relator and the State of Arkansas to recover treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, A.C.A. § 20-77-901 et seq.

193. The Arkansas Medicaid Fraud False Claims Act § 20-77-902 provides liability for any person who-

> Knowingly makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under the Arkansas Medicaid program;
>
> At any time knowingly makes or causes to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment;

194. In addition, A.C.A. § 20-77-902(7)(A) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the Arkansas Medicaid program.

195. Defendants violated the Arkansas Medicaid Fraud False Claims Act § 20-77-902(1) (2) & (7)(A) by engaging in the fraudulent and illegal practices described herein.

196. Defendants furthermore violated Arkansas Medicaid Fraud False Claims Act § 20-77-902(1) & (2) and knowingly caused thousands of false claims to be made, used and presented to Arkansas by its violation of federal and state laws, including A.C.A. § 20-77-902(7)(A) and the AKS, as described herein.

197. Arkansas, by and through the Arkansas Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

198. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to Arkansas in connection with Defendants' fraudulent and illegal practices.

199. Had Arkansas known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

200. As a result of Defendants' violations of § 20-77-902(1) (2) & (7)(A), the State of Arkansas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

201. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to A.C.A. § 20-77-911(a) on behalf of himself and the State of Arkansas.

202. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Arkansas in the operation of its Medicaid program.

203. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF ARKANSAS:

Three times the amount of actual damages which the State of Arkansas has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Arkansas;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to A.C.A. § 20-77-911(a) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT FOUR

VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT

204. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of some or all Defendants.

205. This is a qui tam action brought by Relator and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

206. Cal. Gov't Code § 12651(a) provides liability for any person who—

Knowingly presents, or causes to be presented, to an officer or employee of the state of any political division thereof, a false claim for payment or approval;

Knowingly makes, uses, or causes to be made or used a false record of statement to get a false claim paid or approved by the state or by any political subdivision;

> Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state of by any political subdivision.
>
> Is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

207. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code §§ 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code § 14107.2.

208. Defendants violated Cal Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2 by engaging in the fraudulent and illegal practices described herein.

209. Defendants furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California by its violation of federal and state laws, including Cal. Bus. & Prof. Code §§ 650 and 650.1 and Cal. Welf. & Inst. Code § 14107.2, and the AKS, as described herein.

210. The State of California, by and through the California Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

211. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' fraudulent and illegal practices.

212. Had the State of California known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

213. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars exclusive of interest.

214. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

215. This Court is requested to accept supplemental jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

216. WHERFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF CALIFORNIA:

Three times the amount of actual damages which the State of California has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of California;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT FIVE

VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT

217. Relators re-allege and incorporate the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide, continuous practice of Defendants, some or all of whom conduct business in the State of Colorado. Upon information and belief, some or all of Defendants' actions described herein occurred in Colorado as well.

218. This is a qui tam action brought by Relators and the State of Colorado to recover treble damages and civil penalties under the Colorado Medicaid False Claims Act, Co. St. §§ 25.5-4-304 to 25.5-4-310 *et seq*.

219. Co. St. § 25.5-4-305 provides liability to any person who:

> (a) Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> (c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;
>
> (d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt

without completely knowing that the information on the receipt is true;

(e) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state in connection with the "Colorado Medical Assistance Act" who lawfully may not sell or pledge the property;

(f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act," or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act;"

(g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1).

220. Defendants violated Co. St. § 25.5-4-305 by continuously engaging in the fraudulent and illegal practices described herein.

221. Defendants furthermore violated Co. St. § 25.5-4-305 and knowingly caused hundreds of thousands of false claims to be made, used, and presented to the State of Colorado by its continuous violation of federal and state laws, including the AKS, as described herein.

222. The State of Colorado, by and through the Colorado Medicaid Program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

223. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Colorado in connection with Defendants' fraudulent and illegal practices.

224. Had Colorado known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

225. As a result of Defendants' violations of Co. St. §§ 25.5-4-304 to 25.5-4-310 *et seq.*, the State of Colorado has been damaged in an amount far in excess of millions of dollars exclusive of interest.

226. Defendants did not, within thirty days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

227. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Co. St. § 25.5-4-306 on behalf of themselves and the State of Colorado.

228. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program.

229. WHERFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF COLORADO:

Three times the amount of actual damages which the State of Colorado has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of Colorado;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Co. St. § 25.5-4-305 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SIX

VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS ACT

230. Relator re-alleges and incorporate the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide, continuous practice of Defendants. Some or all of the Defendants conduct business in the State of Connecticut. Upon information and belief, some or all of the Defendants actions described herein occurred in Connecticut as well.

231. This is a qui tam action brought by Relator and the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, C.G.S.A. §§ 17b-301 *et seq*.

232. C.G.S.A. § 17b-301a provides for liability for any persons who:

(1) Knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services;

(2) Knowingly make, use or cause to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;

(3) Conspire to defraud the state by securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;

(4) Having possession, custody or control of property or money used, or to be used, by the state relative to a medical assistance program administered by the Department of Social Services, and intending to defraud the state or willfully to conceal the property, deliver or cause to be delivered less property than the amount for which the person receives a certificate or receipt;

(5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the state relative to a medical assistance program administered by the Department of Social Services and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true;

(6) Knowingly buy, or receive as a pledge of an obligation or debt, public property from an officer or employee of the state relative to a medical assistance program administered by the Department of Social Services, who lawfully may not sell or pledge the property;

(7) Knowingly make, use or cause to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state under a medical assistance program administered by the Department of Social Services.

233. Defendants violated C.G.S.A. § 17b-301a by continuously engaging in the fraudulent and illegal practices described herein.

234. Defendants furthermore violated C.G.S.A. § 17b-301a and knowingly caused hundreds of thousands of false claims to be made, used, and presented to the State of Connecticut by its violation of federal and state laws, including the AKS, as described herein.

235. The State of Connecticut, by and through the Connecticut Medicaid Program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

236. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Connecticut in connection with Defendants' fraudulent and illegal practices.

237. Had Connecticut known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

238. As a result of Defendants' violations of C.G.S.A. § 17b-301, the State of Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

239. Defendants did not, within thirty days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

240. Mr. Ryan Bliss is a private persons with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to C.G.S.A. § 17b-301 on behalf of themselves and the State of Connecticut.

241. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of its Medicaid program.

242. WHERFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF CONNECTICUT:

Three times the amount of actual damages which the State of Connecticut has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of Connecticut;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to C.G.S.A. 17b-301b and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SEVEN

VIOLATIONS OF THE DELAWARE FALSE AND REPORTING CLAIMS ACT

243. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct

business in the State of Delaware. Upon information and belief, some or all of the Defendants' actions described herein occurred in Delaware as well.

244. This is a qui tam action brought by Relator and the State of Delaware to recover treble damages and civil penalties under the Delaware Medicaid False Claims Act, 6 Del. C. § 1201 et seq.

245. 6 Del. C. § 1201 et seq. provides liability for any person who—

> Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved;
>
> Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, increase or decrease an obligation to pay or transmit money or property to or from the Government

246. Further, 31 Del. C. § 1005 provides that—

> It shall be unlawful for any person to offer or pay any remuneration (including any kickback, bribe or rebate) directly or indirectly, in cash or in kind to induce any other person . . . [t]o purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any property, facility, service, or item of medical care or medical assistance for which payment may be made in whole or in part under any public assistance program.

247. Defendants violated 6 Del. C. § 1201 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware by its violation of federal and state laws, including 31 Del. C. §1005 and the AKS as described herein.

248. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

249. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendants' fraudulent and illegal practices.

250. Had the State of Delaware known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

251. As a result of Defendants' violations of 6 Del C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

252. Defendants did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

253. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of himself and the State of Delaware.

254. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

255. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties against Defendants:

To the STATE OF DELAWARE:

Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty on not less than $5,500 and not more than $ 11,000 for each false claim which Defendants caused to be presented to the State of Delaware;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to 6 Del C. § 1205,and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT EIGHT

VIOLATION OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

256. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the District of Columbia. Upon information and belief, some or all of the Defendants' actions described herein occurred in the District of Columbia as well.

257. This is a qui tam action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. § 2-308.13 et seq.

258. D.C. Code § 2-30814(a) provides liability for any person who-

> Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
>
> Knowingly makes, uses or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
>
> Conspires to defraud the District by getting a false claim allowed or paid by the District;
>
> Is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

259. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:

> Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or
>
> Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.

260. Defendants violated D. C. Code § 4-802(c) by engaging in the fraudulent and illegal practices described herein.

261. Defendants furthermore violated D. C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its violation of federal and state laws, including D. C. Code § 4-802(c) and the AKS, as described herein.

262. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

263. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the District of Columbia is connection with Defendants' fraudulent and illegal practices.

264. Had the District of Columbia known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

265. As a result of Defendants' violations of D.C. Code § 2-308.14(a) the District of Columbia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

266. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of himself and the District of Columbia.

267. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

268. WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the DISTRICT OF COLUMBIA:

Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of Columbia;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to D. C. Code § 2-308.15(f) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT NINE

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

269. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Florida. Upon information and belief, some or all of the Defendants' actions described herein occurred in the State of Florida as well.

270. This is a qui tam action brought by Relator and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, West's F.S.A. § 68.081 et seq.

271. West's F.S.A. § 68.082 provides liability for any person who-

Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval

Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency

Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid

272. Defendants violated West's F.S.A. § 68.082 by engaging in the fraudulent and illegal practices described herein.

273. Defendants furthermore violated West's F.S.A. § 68.082 and knowingly caused thousands of false claims to be made, used and presented to the State of Florida by its violation of federal and state laws, including the AKS, as described herein.

274. The State of Florida, by and through the State of Florida Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

275. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendants' fraudulent and illegal practices.

276. Had the State of Florida known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

277. As a result of Defendants' violations of West's F.S.A. § 68.082 the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

278. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to West's F.S.A. § 68.083(2) on behalf of himself and the State of Florida.

279. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

280. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF FLORIDA:

Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Florida;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to West's F.S.A. § 68.085 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TEN

VIOLATION OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

281. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Georgia. Upon information and belief, some or all of the Defendants' actions described herein occurred in Georgia as well.

282. This is a qui tam action brought by Relator and the State of Georgia to recover treble damages and civil penalties under the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

283. Ga. Code Ann. § 49-4-168.1 *et seq.* provides liability for any person who—

> Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
>
> Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia.

284. Defendants violated Ga. Code Ann. § 49-4-168.1 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Georgia by its violation of federal and state laws, including the AKS, as described herein.

285. The State of Georgia, by and through the Georgia Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

286. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendants' fraudulent and illegal practices.

287. Had the State of Georgia known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

288. As a result of Defendants' violations of Ga. Code Ann. § 49-4-168.1, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

289. Defendants did not, within 30 days after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

290. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Ga. Code Ann., § 49-4-168.2(b) on behalf of himself and the State of Georgia.

291. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

292. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties against Defendants:

To the STATE OF GEORGIA:

Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty on not less than $5,500 and not more than $ 11,000 for each false claim which Defendants caused to be presented to the State of Georgia;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Ga. Code Ann., § 49-4-168.2(i),and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT ELEVEN

VIOLATION OF THE HAWAII FALSE CLAIMS ACT

293. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Hawaii. Some or all of the Defendants' actions described herein occurred in Hawaii as well.

294. This is a qui tam action brought by Relator and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661.21 et seq.

295. Haw. Rev. Stat. § 661-21(a) provides liability for any person who—

> Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> Conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
>
> Is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

296. Defendants violated Haw. Rev. Stat. § 661.21(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Hawaii by its violation of federal and state laws, including the AKS, as described herein.

297. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

298. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendants' fraudulent and illegal practices.

299. Had the State of Hawaii known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

300. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21(a) the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

301. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

302. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

303. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF HAWAII:

Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Hawaii;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Haw. Rev. Stat. § 661-27 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWELVE

VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

304. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Illinois. Upon information and belief, some or all of the Defendants' actions described herein occurred in Illinois as well.

305. This is a qui tam action brought by Relator and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*

306. 740 ILCS 175/3(a) provides liability for any person who—

> knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;
>
> knowingly makes, uses, of causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

307. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item of service for which payment may be made in whole or in part under the Illinois Medicaid program.

308. Defendants violated 305 ILCS 5/8A-3(b) by engaging in the fraudulent and illegal practices described herein.

309. Defendants furthermore violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois by their violation of federal and state laws, including 305 ILCS 5/8A-3(b) and the AKS, as described herein.

310. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

311. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendants' fraudulent and illegal practices.

312. Had the State of Illinois known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

313. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars exclusive of interest.

314. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegation of this Complaint, who has brought this action pursuant to 740 ILCS 175/3(b) on behalf of himself and the State of Illinois.

315. This court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

316. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF ILLINOIS:

Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Illinois;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to 740 ILCS/4(d) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT THIRTEEN

VIOLATION OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

317. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all Defendants conduct business in the State of Indiana. Upon information and belief, some or all of the Defendants' actions described herein occurred in Indiana as well.

318. This is a qui tam action brought by Relator and the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 *et seq.*

319. IC 5-11-5.5-2 provides liability for any person who—

> (1) presents a false claim to the state for payment or approval;
>
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
>
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
>
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
>
> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
>
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
>
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
>
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6).

320. In addition, IC 12-15-24-1 & IC 12-15-24-2 prohibits the provision of a kickback or bribe in connection with the furnishing of items or services or the making or receipt of the payment under the Indiana Medicaid program.

321. Defendants violated IC 12-15-24-1 & IC 12-15-24-2 by engaging in the fraudulent and illegal practices described herein.

322. Defendants furthermore violated IC 5-11-5.5-2 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana by its violation

of federal and state laws, including IC 12-15-24-1 & IC 12-15-24-2 and the AKS, as described herein.

323. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

324. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein is an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Defendants' fraudulent and illegal practices.

325. Had the State of Indiana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

326. As a result of Defendants' violations of IC 5-11-5.5-2, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

327. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegation of this Complaint, who has brought this action pursuant to IC 5-11-5.5-4 on behalf of himself and the State of Indiana.

328. This court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

329. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF INDIANA:

Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' fraudulent and illegal practices;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to IC 5-11-5.5-6 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT FOURTEEN

VIOLATION OF THE IOWA FALSE CLAIMS ACT

330. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Iowa. Upon information and belief, some or all of the Defendants' actions described herein occurred in Iowa as well.

331. This is a qui tam action brought by Relator and the State of Iowa to recover treble damages and civil penalties under I.C.A. § 685.1, *et seq.*

332. I.C.A. § 685.2, provides liability, in relevant part, for any person who:

a. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.

b. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

c. Conspires to violate any of these provisions.

333. Defendants violated IC I.C.A. § 685.2 by engaging in the fraudulent and illegal practices described herein.

334. Defendants furthermore violated I.C.A. § 685.2 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana by its violation of federal and state laws, as described herein.

335. The State of Iowa, by and through the Iowa Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

336. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein is an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Iowa in connection with Defendants' fraudulent and illegal practices.

337. Had the State of Iowa known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

338. As a result of Defendants' violations of I.C.A. § 685.2, the State of Iowa has been damaged in an amount far in excess of millions of dollars exclusive of interest.

339. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegation of this Complaint, who has brought this action pursuant to I.C.A. § 685.3 on behalf of himself and the State of Iowa.

340. This court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

341. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties against Defendants:

To the STATE OF IOWA:

Three times the amount of actual damages which the State of Iowa has sustained as a result of Defendants' fraudulent and illegal practices;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to I.C.A. § 685.3 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT FIFTEEN

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

342. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Louisiana. Upon information and belief, some or all of the Defendants' actions described herein occurred in Louisiana as well.

343. This is a qui tam action brought by Relator and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La Rev. Stat. Ann § 437.1 et seq.

344. La. Rev. Stat. Ann. § 438.3 provides –

> No person shall knowingly present or cause to be presented a false or fraudulent claim;
>
> No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds;
>
> No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

345. In addition, La. Rev. Stat. Ann.§ 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

346. Defendants violated La. Rev. Stat. Ann § 438.2(A) by engaging in the fraudulent and illegal practices described herein.

347. Defendants furthermore violated La. Rev. Stat. Ann. § 438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana by their violation of federal and state laws, including La. Rev. Stat. Ann. § 438.2(A) and the AKS, as described herein.

348. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

349. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendants' fraudulent and illegal practices.

350. Had the State of Louisiana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

351. As a result of Defendants' violations of La. Rev. Stat. Ann. § 438.3 the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

352. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. § 439.1(A) on behalf of himself and the State of Louisiana.

353. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

354. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF LOUISIANA:

Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award or reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SIXTEEN

VIOLATIONS OF THE MARYLAND FALSE CLAIMS AGAINST STATE HEALTH PLANS AND STATE HEALTH PROGRAMS ACT

355. Relator re-alleges and incorporate the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relators state that the course of conduct described in this Complaint was a nationwide, continuous practice of Defendants. Some or all of the Defendants conduct business in the State of Maryland. Upon information and belief, some or all of the Defendants' actions described herein occurred in Maryland as well.

356. This is a qui tam action brought by Relator and the State of Maryland to recover treble damages and civil penalties under the Maryland's False Claims Against State Health Plans and State Health Programs Act, MD HG §§ 2-601 *et seq.*

357. MD HG § 2-602(a) provides liability for any person who:

(1) Knowingly presents or cause to be presented a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or cause to be made or used a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation under this subtitle;

(4) Has possession, custody, or control of money or other property used by or on behalf of the State under a State health plan or a State health program and knowingly delivers or cause to be delivered to the State less than all of that money or other property;

(5)(i) Is authorized to make or deliver a receipt or other document certifying receipt of money or other property used or to be used by the State under a State health plan or a State health program; and

(ii) Intending to defraud the State or the Department, makes or delivers a receipt or document knowing that the information contained in the receipt or document is not true;

(6) Knowingly buys or receives as a pledge of an obligation or debt publicly owned property from an officer, employee, or agent of a State health plan or a State health program who lawfully may not sell or pledge the property;

(7) Knowingly makes, uses, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or other property to the State;

(8) Knowingly conceals, or knowingly and improperly avoids or decreases, an obligation to pay or transmit money or other property to the State; or

(9) Knowingly makes any other false or fraudulent claim against a State health plan or a State health program.

358. Defendants violated MD HG § 2-602(a) by continuously engaging in the fraudulent and illegal practices described herein.

359. Defendants furthermore violated MD HG §§ 2-601 *et seq*. and knowingly caused hundreds of thousands of false claims to be made, used, and presented to the State of Maryland by its continuous violation of federal and state laws, including the AKS, as described herein.

360. The State of Maryland, by and through the Maryland Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

361. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Maryland in connection with Merck's fraudulent and illegal practices.

362. Had the State of Maryland known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

363. As a result of Defendants' violations of MD HG §§ 2-601 *et seq.*, the State of Maryland has been damaged in an amount far in excess of millions of dollars exclusive of interest.

364. Mr. Ryan Bliss is a private persons with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to MD HG §§ 2-601 *et seq.*, on behalf of themselves and the State of Maryland.

365. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Maryland in the operation of its Medicaid program.

366. WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MARYLAND:

Three times the amount of actual damages which the State of Maryland has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not more than $10,000 for each false claim which Defendants caused to be presented to the State of Maryland;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to MD HG § 2-602(b)(1) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award or reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT SEVENTEEN

VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT

367. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the Commonwealth of Massachusetts. Upon information and belief, some or all of the Defendants' actions described herein occurred in Massachusetts as well.

368. This is a qui tam action brought by Relator and State of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap 12 § 5(A) et seq.

369. Mass. Gen. Laws Ann. Chap 12 § 5B provides liability for any person who—

Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
Knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

> Conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
>
> Is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reason able time after discovery of the false claim.

370. In addition, Mass. Gen. Laws Ann. Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe ore rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

371. Defendants violated Mass. Gen. Laws Ann. Chap. 118E § 41 by engaging in the fraudulent and illegal practices described herein.

372. Defendants furthermore violated Mass. Gen. Laws Ann. Chap 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Massachusetts by their violation of federal and state laws, including Mass. Gen. Laws Ann. Chap. 118E § 41 and the AKS, as described herein.

373. The State of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

374. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Massachusetts in connection with Defendants' fraudulent and illegal practices.

375. Had the State of Massachusetts known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

376. As a result of Defendants' violations of Mass. Gen. Laws Ann. Chap. 12 § 5B the State of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

377. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to Mass. Gen. Laws Ann Chap. 12 § 5(c(2) on behalf of himself and the State of Massachusetts.

378. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Massachusetts in the operation of its Medicaid program.

379. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MASSACHUSETTS:

Three times the amount of actual damages which that State of Massachusetts has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Massachusetts;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5F and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT EIGHTEEN

VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT

380. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Defendants conduct business in Michigan. Upon information and belief, Defendants' actions described herein occurred in Michigan as well.

381. This is a qui tam action brought by Relator and State of Michigan for treble damages and penalties under Michigan Medicaid False Claim Act, M.C.L.A. 400.601 *et seq.*

382. M.C.L.A. 400.607 provides liability for any person who, among other things—

> Causes to be made or presented to an employee or officer of this state a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws, upon or against the state, knowing the claim to be false.
>
> Presents or causes to be made or presented a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards.

383. In addition, M.C.L.A. 400.604 prohibits the solicitation, receipt or offering of a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part pursuant to the Michigan Medicaid program.

384. Defendants violated M.C.L.A. 400.604 by engaging in the fraudulent and illegal practices described herein.

385. Defendants furthermore violated M.C.L.A. 400.607 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Michigan by their violation of federal and state laws, including M.C.L.A. 400.604 and the AKS, as described herein.

386. The State of Michigan, by and through the Michigan Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

387. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Michigan in connection with Defendants' fraudulent and illegal practices.

388. Had the State of Michigan known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

389. As a result of Defendants' violations of M.C.L.A. 400.607 the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

390. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to M.C.L.A. 400.610a on behalf of himself and the State of Michigan.

391. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

392. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MICHIGAN:

All damages to which the State of Michigan is entitled pursuant to M.C.L.A. 400.612;

Civil penalties for each false claim which Defendants caused to be presented to the State of Michigan;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to M.C.L.A. 400.610a(9) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT NINETEEN

VIOLATION OF THE MONTANA FALSE CLAIMS ACT

393. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in Montana. Upon information and belief, some or all of the Defendants' actions described herein occurred in Montana as well.

394. This is a qui tam action brought by Relator and State of Montana for treble damages and penalties under Montana False Claims Act, MT ST 17-8-401 *et seq.*

395. MT ST 17-8-403 provides liability for any person who—

> knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;
>
> knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;
>
> conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity.

396. In addition, MT ST 45-6-313 prohibits the solicitation, receipt or offering any remuneration, including but not limited to a kickback, bribe, or rebate, other than an amount legally payable under the medical assistance program, for furnishing services or items for which payment may be made under the Montana Medicaid program.

397. Defendants violated MT ST 45-6-313 by engaging in the fraudulent and illegal practices described herein.

398. Defendants furthermore violated MT ST 17-8-403 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Montana by their violation of federal and state laws, including MT ST 45-6-313 and the AKS, as described herein.

399. The State of Montana, by and through the Montana Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

400. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Defendants' fraudulent and illegal practices.

401. Had the State of Montana known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

402. As a result of Defendants' violations of MT ST 17-8-403 the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

403. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to MT ST 17-8-406 on behalf of himself and the State of Montana.

404. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

405. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF MONTANA:

Three times the amount of actual damages which that State of Montana has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of $10,000 for each false claim which Defendants caused to be presented to the State of Montana;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to MT ST 17-8-410 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY

VIOLATION OF THE NEVADA FALSE CLAIMS ACT

406. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Nevada. As set forth above, some or all of the Defendants' actions described herein occurred in Nevada as well.

407. This is a qui tam action brought by Relator and the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010 et. seq.

408. N.R.S. § 357.040(1) provides liability for any person who—

> Knowingly presents or causes to be presented a false claim for payment or approval;
>
> Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;
>
> Conspires to defraud by obtaining allowance or payment of a false claim;
>
> Is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

409. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

410. Defendants violated N.R.S. § 422.560 by engaging in the fraudulent and illegal practices described herein.

411. Defendants furthermore violated N.R.S. § 357.040(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada by their violation of federal and state laws, including N.R.S. § 422.560, and the AKS, as described herein.

412. The State of Nevada, by and through the Nevada Medicaid program and other health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

413. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendants' fraudulent and illegal practices.

414. Had the State of Nevada known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

415. As a result of Defendants' violations of N.R.S. § 357.040(1) the State of Nevada has been damaged in an amount far in excess or millions of dollars exclusive of interest.

416. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of himself and the State of Nevada.

417. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

418. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEVADA:

Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $2,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Nevada;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to N.R.S § 357.210 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-ONE

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT

419. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct

business in the New Hampshire. Upon information and belief, some or all of the Defendants' actions described herein occurred in New Hampshire as well.

420. This is a qui tam action brought by Relator and State of New Hampshire for treble damages and penalties under New Hampshire False Claims Act, N.H. Rev. Stat. § 167:61-b *et seq.*

421. N.H. Rev. Stat. § 167:61-b provides liability for any person who—

> Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.
>
> Conspires to defraud the department by getting a false or fraudulent claim allowed or paid.

422. Defendants violated N.H. Rev. Stat. § 167:61-b and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Hampshire by its violation of federal and state laws, including the AKS as described herein.

423. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

424. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Hampshire in connection with Defendants' fraudulent and illegal practices.

425. Had the State of New Hampshire known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

426. As a result of Defendants' violations of N.H. Rev. Stat. § 167:61-b, the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

427. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to N.H. Rev. Stat. § 167:61-c on behalf of himself and the State of New Hampshire.

428. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

429. WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW HAMPSHIRE:

Three times the amount of actual damages which that State of New Hampshire has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Hampshire;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to N.H. Rev. Stat. § 167:61-e and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-TWO

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

430. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, some or all of the Defendants conduct business in New Jersey. Upon information and belief, some or all of the Defendants' actions described herein occurred in New Jersey as well.

431. This is a qui tam action brought by Relator and State of New Jersey for treble damages and penalties under New Jersey False Claims Act, N.J.S.A. 2A:32C-1 et seq.

432. N.J.S.A. 2A:32C-3 provides liability for any person who—

> Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

433. In addition, N.J.S.A. 30:4D-17 prohibits solicitation, offers, or receipt of any kickback, rebate or bribe in connection with the furnishing of items or services for which payment is or may be made in whole or in part under the New Jersey Medicaid program, or the furnishing of items or services whose cost is or may be reported in whole or in part in order to obtain benefits or payments under New Jersey Medicaid.

434. Defendants violated N.J.S.A. 30:4D-17 by engaging in the fraudulent and illegal practices described herein.

435. Defendants furthermore violated N.J.S.A. 2A:32C-3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada by their violation of federal and state laws, including N.J.S.A. 30:4D-17 and the AKS, as described herein.

436. The State of New Jersey, by and through the New Jersey Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

437. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Defendants' fraudulent and illegal practices.

438. Had the State of New Jersey known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

439. As a result of Defendants' violations of N.J.S.A. 2A:32C-3 the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

440. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to N.J.S.A. 2A:32C-5 on behalf of himself and the State of New Jersey.

441. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

442. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW JERSEY:

Three times the amount of actual damages which that State of New Jersey has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Jersey;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to N.J.S.A. 2A:32C-7and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-THREE

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT AND THE FRAUD AGAINST TAXPAYERS ACT

443. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct

business in the State of New Mexico. Upon information and belief, some or all of the Defendants' actions described herein occurred in the State of New Mexico as well.

444. This is a qui tam action brought by Relator and the State of New Mexico to recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N. M. S. A. 1978, § 27-14-1 *et seq.* and the New Mexico Fraud Against Taxpayers Act, N. M. S. A. 1978, § 44-9-1 *et seq.*

445. N. M. S. A. 1978, § 27-14-4 provides liability for any person who-

> Presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program
>
> Makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false
>
> Conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent

446. N.M.S.A. 1978 § 44-9-3 provides liability for any person who-

> knowingly presents, or causes to be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;
> knowingly makes or uses, or causes to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
>
> conspires to defraud the state by obtaining approval or payment on a false or fraudulent claim;
>
> conspires to make, use or cause to be made or used, a false, misleading or fraudulent record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state.

447. Defendants violated N. M. S. A. 1978, § 27-14-4 and N.M.S.A. 1978 § 44-9-3 by engaging in the fraudulent and illegal practices described herein.

448. Defendants furthermore violated N. M. S. A. 1978, § 27-14-4 and N.M.S.A. 1978 § 44-9-3 and knowingly caused thousands of false claims to be made, used and presented to the State of New Mexico by their violation of federal and state laws, including the AKS, as described herein.

449. The State of New Mexico, by and through the State of New Mexico Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

450. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Defendants' fraudulent and illegal practices.

451. Had the State of New Mexico known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

452. As a result of Defendants' violations of N. M. S. A. 1978, § 27-14-4 and N.M.S.A. 1978 § 44-9-3 the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

453. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N. M. S. A. 1978, § 27-14-7 and N. M. S. A. 1978, § 44-9-5 on behalf of himself and the State of New Mexico.

454. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

455. WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW MEXICO:

Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to N. M. S. A. 1978, § 27-14-9 and N. M. S. A. 1978, § 44-9-7 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-FOUR

VIOLATION OF THE NEW YORK FALSE CLAIMS ACT

456. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct

business in the New York. As set forth above, some or all of the Defendants' actions described herein occurred in New York as well.

457. This is a qui tam action brought by Relator and State of New York for treble damages and penalties under New York False Claims Act, McKinney's State Finance Law § 187 *et seq.*

458. McKinney's State Finance Law § 189 provides liability for any person who—

> Knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;
>
> Conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

459. Defendants violated § 189 by engaging in the fraudulent and illegal practices described herein.

460. Defendants furthermore violated § 189 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New York by their violation of federal and state laws, including the AKS, as described herein.

461. The State of New York, by and through the New York Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

462. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express

condition of payment of claims submitted to the State of New York in connection with Defendants' fraudulent and illegal practices.

463. Had the State of New York known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

464. As a result of Defendants' violations of § 189 the State of New York has been damaged in an amount far in excess of millions of dollars exclusive of interest.

465. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of the Compliant, who has brought this action pursuant to McKinney's State Finance Law § 190(2) on behalf of himself and the State of New York.

466. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

467. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NEW YORK:

Three times the amount of actual damages which that State of New York has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New York;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to McKinney's State Finance Law § 190(6) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-FIVE

VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT

468. Relator re-alleges and incorporate the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator state that the course of conduct described in this Complaint was a nationwide, continuous practice of Defendants. Some or all of the Defendants conduct business in the State of North Carolina. Some or all of the Defendants' actions described herein occurred in the State of North Carolina as well.

469. This is a qui tam action brought by Relator and the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, NC ST §§ 1-605 *et seq.*

470. NC ST § 1-607(a) provides liability for any person who:

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section;
>
> (4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property;
>
> (5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the State, makes or

> delivers the receipt without completely knowing that the information on the receipt is true.
>
> (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who lawfully may not sell or pledge the property.
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

471. Defendants violated NC ST § 1-607(a) by engaging in the fraudulent and illegal practices described herein.

472. Defendants furthermore violated NC ST § 1-607(a) and knowingly caused thousands of false claims to be made, used, and presented to the State of North Carolina by its continuous violation of federal and state laws, including NC ST § 1-607(a) and the AKS, as described herein.

473. The State of North Carolina, by and through the State of North Carolina Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

474. Compliance with applicable Medicare, Medicaid, and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' fraudulent and illegal practices.

475. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

476. As a result of Defendants' violations of NC ST § 1-607(a), the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

477. Defendants did not, within 30 days after they first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

478. Mr. Ryan Bliss is a private persons with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to NC ST § 1-607(a) on behalf of themselves and the State of North Carolina.

479. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

480. WHEREFORE, Relator respectfully request this Court to award the following damages to the following parties and against Defendants:

To the STATE OF NORTH CAROLINA:

Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of North Carolina;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant NC ST § 1-610 and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-SIX

VIOLATION OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT

481. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Oklahoma. Upon information and belief, some or all of the Defendants' actions described herein occurred in the State of Oklahoma as well.

482. This is a qui tam action brought by Relator and the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053 *et seq.*.

483. 63 Okl. St. Ann. § 5053.1 provides liability for any person who-

Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

Conspires to defraud the state by getting a false or fraudulent claim allowed or paid;

484. In addition, 56 Okl. St. Ann. § 1005 prohibits solicitation or acceptance of a benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid Program.

485. Defendants violated 56 Okl. St. Ann. § 1005 by engaging in the fraudulent and illegal practices described herein.

486. Defendants furthermore violated 63 Okl. St. Ann. § 5053.1 and knowingly caused thousands of false claims to be made, used and presented to the State of Oklahoma by their violation of federal and state laws, including 56 Okl. St. Ann. § 1005 and the AKS, as described herein.

487. The State of Oklahoma, by and through the State of Oklahoma Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

488. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' fraudulent and illegal practices.

489. Had the State of Oklahoma known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

490. As a result of Defendants' violations of 63 Okl. St. Ann. § 5053.1 the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

491. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okl. St. Ann. § 5053.2(B) on behalf of himself and the State of Oklahoma.

492. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

493. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF OKLAHOMA:

Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant 63 Okl. St. Ann. § 5053.4 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

FILED UNDER SEAL

COUNT TWENTY-SEVEN

VIOLATION OF THE RHODE ISLAND FALSE CLAIMS ACT

494. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Rhode Island. Upon information and belief, some or all of the Defendants' actions described herein occurred in the State of Rhode Island as well.

495. This is a qui tam action brought by Relator and the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island False Claims Act, Gen. Laws 1956, § 9-1.1-1 *et seq.*

496. Gen. Laws 1956, § 9-1.1-3 provides liability for any person who-

> knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;
>
> knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

497. In addition, Gen. Laws 1956, § 40-8.2-3 prohibits the solicitation, receipt, offer, or payment of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, in cash or in kind, to induce referrals from or to any person in return for furnishing of services or merchandise or in return for referring an individual to a person for the furnishing of any services or merchandise for which payment may be made, in whole or in part, under the Rhode Island Medicaid program.

498. Defendants violated Gen. Laws 1956, § 40-8.2-3 by engaging in the fraudulent and illegal practices described herein.

499. Defendants furthermore violated Gen. Laws 1956, § 9-1.1-3 and knowingly caused thousands of false claims to be made, used and presented to the State of Rhode Island by their violation of federal and state laws, including Gen. Laws 1956, § 40-8.2-3 and the AKS, as described herein.

500. The State of Rhode Island, by and through the State of Rhode Island Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

501. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Defendants' fraudulent and illegal practices.

502. Had the State of Rhode Island known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

503. As a result of Defendants' violations of Gen. Laws 1956, § 9-1.1-3 the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

504. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Gen. Laws 1956, § 9-1.1-4(b) on behalf of himself and the State of Rhode Island.

505. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

506. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF RHODE ISLAND:

Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Rhode Island;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant Gen. Laws 1956, § 9-1.1-4(d) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

COUNT TWENTY-EIGHT

VIOLATION OF THE TENNESSEE FALSE CLAIMS ACT

507. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct

business in the State of Tennessee. Upon information and belief, some or all of the Defendants' actions described herein occurred in Tennessee as well.

508. This is a qui tam action brought by Relator and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.

509. Section 71-5-182(a)(1) provides liability for any person who—

> Presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
>
> Makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for a approved by the state knowing such record or statement is false;
>
> Conspires to defraud the State by getting a claim allowed or paid under the
>
> Medicaid program knowing such claim is false or fraudulent.

510. Defendants violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee by its violation of federal and state laws, including the AKS, as described herein.

511. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

512. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendants' fraudulent and illegal practices.

513. Had the State of Tennessee known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

514. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

515. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

516. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

517. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TENNESSEE:

Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed to Tenn. Code Ann. §71-5-183(c) and/or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this Court deems equitable and just.

COUNT TWENTY-NINE

VIOLATION OF THE TEXAS MEDICAID FALSE CLAIMS ACT

518. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Texas. Some or all of the Defendants' actions described herein occurred in Texas as well.

519. This is a qui tam action brought by Relator and the State of Texas to recover double damages and civil penalties under the Texas False Claims Act, V.T.C.A. Hum. Res. Code § 36.001 et seq.

520. V.T.C.A. Hum. Res. Code § 36.002, in relevant part, provides liability for any person who—

> (1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> (3) knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the

> benefit or payment to a use other than for the benefit of the person on whose behalf it was received
>
> * * *
>
> (5) except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;
>
> * * *
>
> (5) except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;
>
> * * *
>
> (9) knowingly enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent;
>
> * * *
>
> (12) knowingly makes, uses, or causes the making or use of a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to this state under the Medicaid program.

521. Defendants violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas by their violation of federal and state laws, including, the AKS, as described herein.

522. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third party payers in connection therewith.

523. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' fraudulent and illegal practices.

524. Had the State of Texas known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

525. As a result of Defendants' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

526. Defendants did not, within 30 days after they first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

527. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

528. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

529. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF TEXAS:

Damages at two times the value of any payment or monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful acts set forth above, as provided by the Texas Human Resources Code § 36.052(a)(1) & (4)

Civil penalties of $15,000 for each and every unlawful act set forth above that resulted in injury to a person younger than 18 years of age, as provided by the Texas Human Resources Code § 36.052(3)(A)

Pre- and post-judgment interest, Tex. Hum. Res. Code § 36.052(a)(2),

To RELATOR:

The maximum amount allowed pursuant to V.T.C.A. Hum Res. Code § 36.110(a), and/or any other applicable provision of law;

Reimbursement for reasonable expenses and costs which Relator incurred in connection with this action, Tex Hum Res. Code §§ 36.007 & 36.110(c);

Reasonable attorneys' fees which the Relator necessarily incurred in bringing and pressing this case, Tex Hum Res. Code §§ 36.007 & 36.110(c); and

Such further relief as this Court deems equitable and just.

COUNT THIRTY

VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

530. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the Commonwealth of Virginia. Upon information and belief, some or all of the Defendants' actions described herein occurred in the Commonwealth of Virginia as well.

531. This is a qui tam action brought by Relator and the Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq.

532. Va. Code Ann. § 8.01-216.3 provides liability for any person who-

> Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
>
> Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth
>
> Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid

533. Defendants violated Va. Code Ann. § 8.01-216.3 by engaging in the fraudulent and illegal practices described herein.

534. Defendants furthermore violated Va. Code Ann. § 8.01-216.3 and knowingly caused thousands of false claims to be made, used and presented to the Commonwealth of Virginia by their violation of federal and state laws, including the AKS, as described herein.

535. The Commonwealth of Virginia, by and through the Commonwealth of Virginia Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

536. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia is connection with Defendants' fraudulent and illegal practices.

537. Had the Commonwealth of Virginia known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

538. As a result of Defendants' violations of Va. Code Ann. § 8.01-216.3 the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

539. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Va. Code Ann. § 8.01-216.5(A) on behalf of himself and the Commonwealth of Virginia

540. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

541. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the COMMONWEALTH OF VIRGINIA:

Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant to Va. Code Ann. § 8.01-216.7 and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

FILED UNDER SEAL

COUNT THIRTY-ONE

VIOLATION OF THE WISCONSIN CLAIMS FOR MEDICAL ASSISTANCE ACT

542. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if fully set forth herein. Additionally, Relator states that the course of conduct described in this Complaint was a nationwide practice of Defendants. Some or all of the Defendants conduct business in the State of Wisconsin. Upon information and belief, some or all of the Defendants' actions described herein occurred in the State of Wisconsin as well.

543. This is a qui tam action brought by Relator and the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Act, W.S.A. 20.931 *et seq.*

544. W.S.A. 20.931(2) provides liability for any person who-

> Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
>
> Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
>
> Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

545. In addition, W.S.A. 49.49(2) prohibits solicitation or receipt of any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under any Wisconsin medical assistance program.

546. Defendants violated W.S.A. 49.49(2) by engaging in the fraudulent and illegal practices described herein.

547. Defendants furthermore violated W.S.A. 20.931(2) and knowingly caused thousands of false claims to be made, used and presented to the State of Wisconsin by their violation of federal and state laws, including W.S.A. 49.49(2) and the AKS, as described herein.

548. The State of Wisconsin, by and through the State of Wisconsin Medicaid program and other state health care programs, and unaware of Defendants' fraudulent and illegal practices, paid the claims submitted by health care providers and third payers in connection therewith.

549. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Defendants' fraudulent and illegal practices.

550. Had the State of Wisconsin known that Defendants were violating the federal and state laws cited herein, it would not have paid the claims submitted by health care providers and third party payers in connection with Defendants' fraudulent and illegal practices.

551. As a result of Defendants' violations of W.S.A. 20.931(2) the State of Wisconsin has been damaged in an amount far in excess of millions of dollars exclusive of interest.

552. Mr. Ryan Bliss is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to W.S.A. 20.931(5) on behalf of himself and the State of Wisconsin.

553. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

554. WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the STATE OF WISCONSIN:

Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendants' fraudulent and illegal practices;

A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Wisconsin;

Prejudgment interest; and

All costs incurred in bringing this action.

To RELATOR:

The maximum amount allowed pursuant W.S.A. 20.931(11) and /or any other applicable provision of law;

Reimbursement for reasonable expenses which Relator incurred in connection with this action;

An award of reasonable attorneys' fees and costs; and

Such further relief as this court deems equitable and just.

DEMAND FOR JURY TRIAL

Relator hereby demands a jury trial.

FILED UNDER SEAL

Dated: July 23, 2013

Respectfully submitted,

UNITED STATES OF AMERICA
ex rel. Ryan Bliss

By: Dan Hargrove

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